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

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

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2018–0039]

Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security/ALL–039 Foreign Access Management System of Records

AGENCY: Department of Homeland Security.

ACTION: Final rule.

SUMMARY: The Department of Homeland Security (DHS) is issuing a final rule to amend its regulations to exempt portions of an updated and reissued system of records titled, “Department of Homeland Security/ALL–039 Foreign Access Management System of Records” from certain provisions of the Privacy Act. Specifically, the Department exempts portions of the “Department of Homeland Security/ALL–039 Foreign Access Management System of Records” from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: This final rule is effective July 27, 2018.

FOR FURTHER INFORMATION CONTACT: For general and privacy-related questions please contact: Philip S. Kaplan, Privacy@hq.dhs.gov, (202) 343–1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

Background

DHS published a notice of proposed rulemaking (NPRM) in the **Federal Register** (83 FR 19020, May 1, 2018) proposing to exempt portions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative

enforcement requirements. The system of records is the DHS/ALL–039 Foreign Access Management System of Records. The DHS/ALL–039 Foreign Access Management System of Records system of records notice (SORN) was published in the **Federal Register** (83 FR 19078, May 1, 2018) and comments were invited on both the NPRM and SORN.

Public Comments

DHS received no comments on the NPRM and no comments on the SORN. After consideration of the lack of public comments, the Department will implement the rulemaking as proposed.

List of Subjects in 6 CFR Part 5

Freedom of information, Privacy.

For the reasons stated in the preamble, DHS amends Chapter I of Title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

■ 1. The authority citation for part 5 is revised to read as follows:

Authority: 6 U.S.C. 101 *et seq.*; Pub. L. 107–296, 116 Stat. 2135; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

■ 2. Add paragraph 78 to appendix C to part 5 to read as follows:

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

78. The DHS/ALL–039 Foreign Access Management System of Records consists of electronic and paper records and will be used by DHS and its components. The DHS/ALL–039 Foreign Access Management System of Records is a repository of information held by DHS in connection with its several and varied missions and functions, including, but not limited to the enforcement of civil and criminal laws; investigations, inquiries, and proceedings there under; and national security and intelligence activities. The DHS/ALL–039 Foreign Access Management System of Records contains information that is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information collected by other federal, state, local, tribal, foreign, or international government agencies. The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(k)(1), (k)(2), and (k)(5), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I); and (f). When a record received from

another system has been exempted in that source system under 5 U.S.C. 552a(j)(2), DHS will claim the same exemptions for those records that are claimed for the original primary systems of records from which they originated and claims any additional exemptions set forth here. Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process. When an investigation has been completed, information on disclosures made may continue to be exempted if the fact that an investigation occurred remains sensitive after completion.

(b) From subsection (d) (Access and Amendment to Records) because access to the records contained in this system of records could inform the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS or another agency. Access to the records could permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension. Amendment of the records could interfere with ongoing investigations and law enforcement activities and would impose an unreasonable administrative burden by requiring investigations to be continually reinvestigated. In addition, permitting access and amendment to such information could disclose security-sensitive information that could be detrimental to homeland security.

(c) From subsection (e)(1) (Relevancy and Necessity of Information) because in the course of investigations into potential violations of federal law, the accuracy of information obtained or introduced occasionally may be unclear, or the information may not be strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of unlawful activity.

(d) From subsections (e)(4)(G), (e)(4)(H), and (e)(4)(I) (Agency Requirements) and (f)

(Agency Rules), because portions of this system are exempt from the individual access provisions of subsection (d) for the reasons noted above, and therefore DHS is not required to establish requirements, rules, or procedures with respect to such access. Providing notice to individuals with respect to existence of records pertaining to them in the system of records or otherwise setting up procedures pursuant to which individuals may access and view records pertaining to themselves in the system would undermine investigative efforts and reveal the identities of witnesses, and potential witnesses, and confidential informants.

Philip S. Kaplan,
Chief Privacy Officer, Department of
Homeland Security.

[FR Doc. 2018-16024 Filed 7-26-18; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0286; Product Identifier 2018-CE-008-AD; Amendment 39-19340; AD 2018-15-08]

RIN 2120-AA64

Airworthiness Directives; Pacific Aerospace Limited Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Pacific Aerospace Limited Model 750XL airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as airplane sound insulation materials attached to the aft face of the firewall not complying with the applicable burn testing criteria for materials on the cabin side of the firewall. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective August 31, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of August 31, 2018.

ADDRESSES: You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0286; or in person at Docket Operations, U.S. Department of Transportation,

Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

For service information identified in this AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; phone: +64 7843 6144; fax: +64 843 6134; email: pacific@aerospace.co.nz; internet: www.aerospace.co.nz. You may view this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available on the internet at <http://www.regulations.gov> by searching for Docket No. FAA-2018-0286.

FOR FURTHER INFORMATION CONTACT: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4144; fax: (816) 329-4090; email: mike.kiesov@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Pacific Aerospace Limited Model 750XL airplanes. The NPRM was published in the **Federal Register** on April 11, 2018 (83 FR 15517). The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country. The MCAI states:

The sound insulation material on the aft face of the firewall must comply with the applicable burn test criteria specified in FAR [14 CFR] 23.853(f). [As of August 30, 2017, § 23.853 was replaced by § 23.2325 (81 FR 96572, December 30, 2016).]

Inspect the aft face of the firewall and determine if sound insulation material is installed per the instructions in Pacific Aerospace Mandatory Service Bulletin (MSB) PACSB/XL/095 issue 1, dated 21 December 2017, or later approved revision.

If a layer of black foam insulating material is found covering the firewall, then remove the material per the instructions in MSB PACSB/XL/095 before further flight.

The MCAI can be found in the AD docket on the internet at: <https://www.regulations.gov/document?D=FAA-2018-0286-0002>.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or

on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting the AD as proposed.

Related Service Information Under 1 CFR Part 51

We reviewed Pacific Aerospace Service Bulletin PACSB/XL/095, Issue 1, dated December 21, 2017. The service information describes procedures for inspection of the airplane sound insulation attached to the aft face of the firewall and removal if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD will affect 22 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this AD. The average labor rate is \$85 per work-hour.

Based on these figures, we estimate the cost of this AD on U.S. operators to be \$1,870, or \$85 per product.

In addition, we estimate that any necessary follow-on actions would take about 8 work-hours, for a cost of \$680 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

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

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

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C.

In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to small airplanes, gliders, balloons, airships, domestic business jet transport airplanes, and associated appliances to the Director of the Policy and Innovation Division.

Regulatory Findings

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

For the reasons discussed above, I certify this AD:

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

(2) Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

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

Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2018–0286; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (telephone (800) 647–5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2018–15–08 Pacific Aerospace Limited:
Amendment 39–19340; Docket No. FAA–2018–0286; Product Identifier 2018–CE–008–AD.

(a) Effective Date

This AD becomes effective August 31, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pacific Aerospace Limited Model 750XL airplanes, all serial numbers up to and including 215, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 54: Nacelles/Pylons.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and address an unsafe condition on an aviation product. The MCAI describes the unsafe condition as airplane sound insulation materials attached to the aft face of the firewall not complying with the applicable burn testing criteria for materials on the cabin side of the firewall. We are issuing this AD to prevent the spread of fire into the cabin in case of an engine fire.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) and (2) of this AD:

(1) Within 90 days after August 31, 2018 (the effective date of this AD), inspect the aft face of the firewall and determine if the sound insulation material is installed per the Inspection Instructions in Pacific Aerospace Service Bulletin PACSB/XL/095, Issue 1, dated December 21, 2017.

(2) If a layer of black foam insulating material is found covering the firewall during the inspection required in paragraph (f)(1) of this AD, before further flight, remove the material per the Accomplishment Instructions in Pacific Aerospace Service Bulletin PACSB/XL/095, Issue 1, dated December 21, 2017.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Small Airplane Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

Send information to ATTN: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; email: mike.kiesov@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, Small Airplane Standards Branch, FAA; or the Civil Aviation Authority of New Zealand (CAA).

(h) Related Information

Refer to MCAI CAA AD DCA/750XL/27A, dated March 1, 2018, for related information. You may examine the MCAI on the internet at: <https://www.regulations.gov/document?D=FAA-2018-0286-0002>.

(i) Material Incorporated by Reference

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

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

(i) Pacific Aerospace Service Bulletin PACSB/XL/095, Issue 1, dated December 21, 2017.

(ii) Reserved.

(3) For Pacific Aerospace Limited service information identified in this AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; phone: +64 7843 6144; fax: +64 843 6134; email: pacific@aerospace.co.nz; internet: www.aerospace.co.nz.

(4) You may view this service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. In addition, you can access this service information on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2018–0286.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on July 20, 2018.

Pat Mullen,

Aircraft Certification Service, Acting Deputy Director, Policy & Innovation Division, AIR–601.

[FR Doc. 2018–15980 Filed 7–26–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2018-0291; Airspace
Docket No. 18-AGL-10]

RIN 2120-AA66

Amendment of Class E Airspace; Ionia, MI

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace extending upward from 700 feet above the surface at Ionia County Airport, Ionia, MI. This action as the result of an airspace review due to the decommissioning of the Lansing VHF omnidirectional range (VOR) navigation aid as part of the VOR Minimum Operational Network (MON) Program. The geographic coordinates of the airport are also updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, November 8, 2018. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11B at NARA, call (202) 741-6030, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222-5711.

SUPPLEMENTARY INFORMATION:**Authority for This Rulemaking**

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

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (83 FR 18763; April 30, 2018) for Docket No. FAA-2018-0291 to amend Class E airspace extending upward from 700 feet above the surface at Ionia County Airport, Ionia, MI. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 modifies Class E airspace extending upward from 700 feet above the surface to within a 6.5-mile radius (decreased from a 7.4-mile radius) at Ionia County Airport, Ionia, MI. The geographic coordinates of the airport are also

updated to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review caused by the decommissioning of the Lansing VOR as part of the VOR MON Program.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B,

Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

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

* * * * *

AGL MI E5 Ionia, MI [Amended]

Ionia County Airport, MI
(Lat. 42°56'17" N, long. 85°03'38" W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Ionia County Airport.

Issued in Fort Worth, Texas, on July 19, 2018.

Walter Tweedy,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

[FR Doc. 2018-16010 Filed 7-26-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2018-0310; Airspace
Docket No. 18-ASW-7]

RIN 2120-AA66

Revocation of Class E Airspace; Clarendon, TX

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action removes Class E airspace extending upward from 700 feet above the surface at Clarendon Municipal Airport, Clarendon, TX. This action is due to the cancellation of the instrument procedures at the airport making this airspace no longer necessary.

DATES: Effective 0901 UTC, November 8, 2018. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the

National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11B at NARA, call (202) 741-6030, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

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

FOR FURTHER INFORMATION CONTACT:

Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222-5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (83 FR 18765; April 30, 2018) for Docket No. FAA-2018-0310 to remove Class E airspace extending upward from 700 feet above the surface at Clarendon Municipal Airport, Clarendon, TX. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraphs 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11B, Airspace Designations and

Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 removes the Class E airspace extending upward from 700 feet above the surface at Clarendon Municipal Airport, Clarendon, TX.

This action due to the cancellation of the instrument procedures at the airport making the airspace no longer necessary.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

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

* * * * *

ASW TX E5 Clarendon, TX [Removed]

Issued in Fort Worth, Texas, on July 16, 2018.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2018–16019 Filed 7–26–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–1083; Airspace Docket No. 17–ACE–13]

RIN 2120–AA66

Amendment of Class D and E Airspace; Kansas City, MO; and Revocation of Class E Airspace; Kansas City, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class D airspace at Charles B. Wheeler Downtown Airport, Kansas City, MO; removes Class E airspace designated as an extension to Class D airspace at Charles B. Wheeler Downtown Airport; and modifies Class E airspace extending upward from 700 feet above the surface at Kansas City International Airport, Kansas City, MO, and Charles B. Wheeler Downtown Airport. This action is required due to the decommissioning of the Riverside VHF omnidirectional range (VOR) facility, which provided navigation guidance for the instrument procedures to Charles B. Wheeler Downtown Airport. The VOR has been

decommissioned as part of the VOR Minimum Operational Network (MON) Program. Additionally, the geographic coordinates and airport name are being updated to coincide with the FAA's aeronautical database. This action is necessary for the safety and management of instrument flight rules (IFR) operations at these airports.

DATES: Effective 0901 UTC, November 8, 2018. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11B at NARA, call (202) 741–6030, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

City International Airport, Kansas City, MO.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (83 FR 4611; February 1, 2018) for Docket No. FAA–2017–1083 to modify Class D airspace at Charles B. Wheeler Downtown Airport, Kansas City, MO; remove Class E airspace designated as an extension to Class D airspace at Charles B. Wheeler Downtown Airport; and modify Class E airspace extending upward from 700 feet above the surface at Kansas City International Airport, Kansas City, MO, and Charles B. Wheeler Downtown Airport. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment was received from the Aircraft Owners and Pilots Association (AOPA). In their comment, AOPA stated that the NPRM did not comply with FAA guidance in FAA Order 7400.2L, Procedures for Handling Airspace Matters, because a graphic was not included in the docket. Additionally, AOPA encouraged the FAA to follow their guidance in the Order by making the action effective date coincidental to the sectional chart publication date.

The FAA has determined AOPA's comments raised no substantive issues with respect to the proposed changes to the airspace addressed in the NPRM. To the extent the FAA failed to follow its policy guidance reference publishing graphics in the docket and establishing the Class D airspace effective date to match the sectional chart date, we note the following.

With respect to AOPA's comment addressing graphics, FAA Order 7400.2L, paragraph 2–3–3.c. requires the official docket to include available graphics. For this airspace action, no graphics were deemed necessary or produced in the review or development of the proposed airspace amendments noted in the NPRM; therefore, no graphics were available to include in the docket.

Specific to AOPA's comment regarding the FAA already creating a graphical depiction of new or modified airspace overlaid on a Sectional Chart for quality assurance purposes, this is not correct nor required in all cases. During the airspace reviews, airspace graphics may be created, if deemed necessary, to determine if there are any terrain issues, or if cases are considered complex. However, in many cases when developing an airspace amendment proposal, a graphic is not required. It was unclear if the graphic AOPA argued

was already created with a sectional chart background was actually the airspace graphic created by the Aeronautical Informational Services office in preparation of publishing the sectional charts. However, that graphic is normally created after the rulemaking determination is published.

With respect to AOPA's comment addressing effective dates, FAA Order 7400.2L, paragraph 2–3–7.a.4. states that, to the extent practicable, Class D airspace area and restricted area rules should become effective on a sectional chart date and that consideration should be given to selecting a sectional chart date that matches a 56-day en route chart cycle date. The FAA does consider publishing Class D airspace amendment effective dates to coincide with the publication of sectional charts, to the extent practicable; however, this consideration is accomplished after the NPRM comment period ends in the final rule. Substantive comments received to NPRMs, flight safety concerns, management of IFR operations at affected airports, and immediacy of required proposed airspace amendments are some of the factors that must be taken into consideration when selecting the appropriate effective date. After considering all factors, the FAA may determine that selecting an effective date that conforms to a 56-day en route chart cycle date that is not coincidental to sectional chart dates is better for the National Airspace System and its users than awaiting the next sectional chart date.

Class D and E airspace designations are published in paragraph 5000, 6004, and 6005, respectively, of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to title 14, Code of Federal Regulations (14 CFR) part 71:

Amends the Class D airspace at Charles B. Wheeler Downtown Airport by updating the header of the airspace legal description to Kansas City, MO, (from Kansas City Charles B. Wheeler Downtown Airport, MO) to comply with FAA Order 7400.2L; adds an extension 1.0 mile each side of the 012° bearing from the Charles B. Wheeler Downtown RWY 19 LOC from the 4.2-mile radius to 4.4 miles from the airport; adds an extension 1.0 mile each side of the 013° bearing from the airport from the 4.2-mile radius to 4.3 miles north of the airport; adds an extension 1.0 mile each side of the 215° bearing from the Charles B. Wheeler Downtown RWY 03 LOC from the 4.2-mile radius to 4.5 miles northeast of the airport; adds an extension 1.0 mile each side of the 218° bearing from the airport from the 4.2-mile radius to 5.0 miles south of the airport; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Removes the Class E airspace designated as an extension to Class D airspace at Charles B. Wheeler Downtown Airport as the airspace is no longer required; and

Amends Class E airspace extending upward from 700 feet above the surface at Kansas City, MO, by updating the header of the airspace legal description to Kansas City, MO, (from Kansas City International Airport, MO) to comply with FAA Order 7400.2L; updates the name and geographic coordinates of Charles B. Wheeler Downtown Airport (formerly Kansas City Downtown Airport) and the geographic coordinates of Sherman Army Airfield (AAF), KS, to coincide with the FAA's aeronautical database; removes the Kansas City VORTAC, DOTTE LOM, Riverside VOR/DME ILS RWY 19R localizer, ILS RWY 19 localizer, ILS RWY 1L localizer, and ILS RWY 1R localizer from the airspace description; removes all current extensions at Kansas City International Airport and Charles B. Wheeler Downtown Airport; and adds an extension 2.0 miles each side of the 215° bearing from the Charles B. Wheeler Downtown RWY 03 LOC from the 6.7-mile radius to 8.7 miles south of Charles B. Wheeler Downtown Airport.

Airspace reconfiguration is necessary due to the decommissioning of the Riverside VOR as part of the VOR MON Program and for the safety and management of IFR operations at these airports.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are

necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ACE MO D Kansas City, MO [Amended]

Charles B. Wheeler Downtown Airport, MO
(Lat. 39°07'23" N, long. 94°35'34" W)
Charles B. Wheeler Downtown RWY 19 LOC
(Lat. 39°06'50" N, long. 94°35'44" W)

Charles B. Wheeler Downtown RWY 03 LOC
(Lat. 39°07'40" N, long. 94°35'17" W)

That airspace extending upward from the surface to and including 3,300 feet MSL within a 4.2-mile radius of Charles B. Wheeler Downtown Airport, excluding that airspace within the Kansas City, MO Class B airspace area; and within 1.0 mile each side of the 012° bearing from the Charles B. Wheeler Downtown RWY 19 LOC, extending from the 4.2-mile radius to 4.4 miles north of the airport; and within 1.0 mile each side of the 013° bearing from the airport, extending from the 4.2-mile radius to 4.3 miles north of the airport; and within 1.0 mile each side of the 215° bearing from the Charles B. Wheeler Downtown RWY 03 LOC, extending from the 4.2-mile radius to 4.5 miles south of the airport; and within 1.0 mile each side of the 218° bearing from the airport, extending from the 4.2-mile radius to 5.0 miles south of the airport.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ACE MO E4 Kansas City Charles B. Wheeler Downtown Airport, MO [Removed]

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

* * * * *

ACE MO E5 Kansas City, MO [Amended]

Kansas City International Airport, MO
(Lat. 39°17'51" N, long. 94°42'50" W)
Charles B. Wheeler Downtown Airport, MO
(Lat. 39°07'23" N, long. 94°35'34" W)
Charles B. Wheeler Downtown RWY 03 LOC
(Lat. 39°07'40" N, long. 94°35'17" W)
Sherman Army Airfield (AAF), KS
(Lat. 39°22'03" N, long. 94°54'52" W)

That airspace extending upward from 700 feet above the surface within a 7.6-mile radius of Kansas City International Airport; and within a 6.7-mile radius of Charles B. Wheeler Downtown Airport; and within 2.0 miles each side of the 215° bearing from the Charles B. Wheeler Downtown RWY 03 LOC, extending from the 6.7-mile radius to 8.7 miles south of Charles B. Wheeler Downtown Airport; and within a 6.5-mile radius of Sherman AAF.

Issued in Fort Worth, Texas, on July 16, 2018.

Walter Tweedy,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

[FR Doc. 2018–16013 Filed 7–26–18; 8:45 am]

BILLING CODE 4910–13–P

MILLENNIUM CHALLENGE CORPORATION

22 CFR Part 1304

Freedom of Information Act Regulations

AGENCY: Millennium Challenge Corporation.

ACTION: Final rule.

SUMMARY: This rule amends the Agency's regulations under the Freedom of Information Act (FOIA). The regulation has been revised to update and implement the relevant provisions of the Freedom of Information Act as required under that statute. This document will assist interested parties in obtaining access to Millennium Challenge Corporation public records.

DATES: This rule is effective July 27, 2018.

FOR FURTHER INFORMATION CONTACT: Tamiko N.W. Watkins, Chief FOIA Officer, 202–521–3730.

SUPPLEMENTARY INFORMATION: The Millennium Challenge Act (MCA) of 2003 established a new federal agency called the Millennium Challenge Corporation. Congress enacted the Freedom of Information Act (FOIA) in 1966 and last modified it with the FOIA Improvement Act of 2016. This rule addresses electronically available documents, procedures for making requests, agency handling of requests, records not disclosed, changes in fees, and public reading rooms, as well as, other related provisions.

Discussion of Final Rule and Response to Comments and Other Changes From Proposed Rule

MCC reviewed all public comments and made the necessary revisions in order to ensure that this rule complies with the Freedom of Information Act and FOIA Improvement Act of 2016. These revisions include updating definitions to reflect the definitions identified in the Department of Justice Template for Agency FOIA Regulations.

Lists of Subjects in 22 CFR Part 1304

Freedom of Information Act procedures.

■ For the reasons set forth in the preamble, the Millennium Challenge Corporation amends chapter XIII of title 22 by revising part 1304 to read as follows:

PART 1304—PRODUCTION OR DISCLOSURE OF INFORMATION

Subpart A—Procedures for Requests for Disclosure of Records Under the Freedom of Information Act

Sec.

- 1304.1 General provisions.
- 1304.2 Definitions.
- 1304.3 Proactive disclosure of MCC records.
- 1304.4 Requirements for making requests.
- 1304.5 Responsibility for acknowledgment and initial determinations.
- 1304.6 Timing of responses to requests.

- 1304.7 Responses to requests.
- 1304.8 Confidential commercial information.
- 1304.9 Administrative appeals.
- 1304.10 Preservation of records.
- 1304.11 Fees.
- 1304.12 Other rights and services.

Subpart B—[Reserved]

Authority: 5 U.S.C. 552, as amended.

§ 1304.1 General provisions.

This part contains the rules that the Millennium Challenge Corporation (“MCC”) follows in processing requests for records under the Freedom of Information Act (“FOIA”) (5 U.S.C. 552). The rules in this part should be read in conjunction with the text of the FOIA and the Uniform Freedom of Information Act Fee Schedule and Guidelines published by the Office of Management and Budget (“OMB Fee Guidelines”). In addition, the MCC FOIA web page contains information about the specific procedures particular to MCC with respect to making FOIA requests. This resource is available at www.mcc.gov/resources/foia.

§ 1304.2 Definitions.

Administrative appeal. An independent review of the initial determination made in response to a FOIA request.

Agency. Any executive department, military department, government corporation, government controlled corporation, or other establishment in the executive branch of the Federal Government or any independent regulatory agency.

Business day or work day. A day of the week, excluding Saturday, Sunday, or legal public holidays.

Calendar days. Every day within a month, including Saturday, Sunday, and legal public holidays. Unless identified as a “business day” or “work day,” all timeframes and days noted in this part shall be calculated in calendar days.

Chief FOIA Officer. A designated MCC employee who is a senior official, at the Assistant Secretary or equivalent level who, subject to the authority of the head of the agency, shall have agency wide responsibility for efficient and appropriate compliance with the FOIA. In addition, the Chief FOIA Officer shall monitor implementation of the FOIA throughout MCC and keep the head of the agency, the chief legal officer of the agency, and the Attorney General appropriately informed of the agency's performance in implementing the FOIA; recommend to the head of the agency such adjustments to MCC's practices, policies, personnel, and funding as may

be necessary to improve its implementation of the FOIA; facilitate public understanding of the purposes of the statutory exemptions of the FOIA; offer training to MCC staff regarding their responsibilities under the FOIA, serve as the primary agency liaison with the Office of Government Information Services and the Office of Information policy; and designate one (1) or more FOIA Public Liaisons. The Chief FOIA Officer shall review, not less frequently than annually, all aspects of the administration of the FOIA by MCC to ensure compliance with the requirements of the FOIA, including—agency regulations; disclosure of records; assessment of fees and determination of eligibility for fee waivers; timely processing of requests for information; the use of exemptions; and dispute resolution services with the assistance of the Office of Government Information Services or the FOIA Public Liaison.

Commercial requester. Any person making a request for information for a use or purpose that furthers a commercial, trade, or profit interest, which can include furthering those interests through litigation.

Complex request. A FOIA request that MCC anticipates will involve a voluminous amount of material to review or will be time-consuming to process.

Confidential commercial information. Records provided to the government that contain material exempt from disclosure under Exemption 4 of the FOIA and disclosure of such records could reasonably be expected to cause substantial competitive harm.

Consultation. When MCC locates a record that contains information of interest to another agency, MCC shall ask the interested agency for their views on disclosing the records before any final determination is made.

Direct costs. Expenditures actually incurred by MCC for searching, duplicating, and in the case of commercial use requests, reviewing records in order to respond to a FOIA request.

Discretionary disclosure. The release of or portions of records to a FOIA requester that could be withheld by MCC under one or more of the FOIA exemptions.

Duplication. The process of making a copy of a record in order to respond to a FOIA request, including but not limited to paper copies, microfilm, audio-video materials, and computer diskettes or other electronic copies.

Duplication fees. The estimated direct costs of making a copy of a record in order to respond to a FOIA request.

Educational institution. Any school or institution that operates a program of scholarly research. A requester in this category must show that the request is made in connection with his or her role at the educational institution.

Educational requester. A student who makes a request in furtherance of their coursework or other school-sponsored activities and provides a copy of a course syllabus or other reasonable documentation to indicate the research purpose for the request, would qualify as part of this fee category.

Exemptions. Certain categories of information that are not required to be released in response to a FOIA request because release would be harmful to governmental or private interests.

Fee waiver. The waiver or reduction of processing fees if a requester can demonstrate that certain statutory standards are satisfied including that the information is in the public interest and is not requested for a commercial interest.

FOIA Appeals Officer. The MCC employee who is responsible for conducting an independent review of the initial determination of the FOIA request after the requester has requested an administrative appeal.

FOIA Public Liaison. The MCC employee who is responsible for assisting in the resolution of disputes in response to FOIA requests.

FOIA Program Officer. The MCC employee who receives and processes requests within the MCC FOIA Office.

Non-commercial scientific institution. An institution that does not operate on a commercial basis, but operates solely for the purpose of conducting scientific research and the results of the scientific research are not intended to promote any particular product or industry.

Record. Any item, collection, or grouping of information maintained by MCC in any form or format, including an electronic copy. A “record” can potentially constitute an entire document, a single page of a multipage document, an individual paragraph of a document, or an email within an email chain.

Referral. When an agency locates a record that originated with, or is of otherwise primary interest to another agency, it will forward that record to the other agency to process the record and to provide the final determination directly to the requester.

Representative of the news media. Any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. The term “news” means

information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations that broadcast “news” to the public at large and publishers of periodicals that disseminate “news” and make their products available through a variety of means to the general public, including news organizations that disseminate solely on the internet. A request for records supporting the news-dissemination function of the requester will not be considered to be for a commercial use. “Freelance” journalists who demonstrate a solid basis for expecting publication through a news media entity will be considered as a representative of the news media. A publishing contract would provide the clearest evidence that publication is expected; however, agencies can also consider a requester’s past publication record in making this determination.

Review. The process of examining a record to determine whether all or part of the record may be released or withheld, and includes redacting or otherwise processing the record for disclosure to a requester. The review process does not include time spent resolving legal or policy issues regarding the application of exemptions to a record. The review process also does not include time spent reviewing records at the administrative appeal level unless, MCC determines that the exemption under which it withheld records does not apply and the records are reviewed again to determine whether a different exemption may apply.

Requester category. One of the three categories that agencies place requesters in for the purpose of determining whether a requester will be charged fees for search, review and duplication, including commercial requesters; non-commercial scientific or educational institutions or news media requesters, and all other requesters.

Search. The time spent locating records that may be responsive to a request, manually or by electronic means, including page-by-page or line-by-line identification of responsive material within a record.

Search fees. Estimated direct costs of the time spent locating records by either manual or electronic means.

Submitter. Any person or entity who provides information directly or indirectly to MCC. The term includes, but is not limited to, corporations, state governments, and foreign governments.

§ 1304.3 Proactive disclosure of MCC records.

Records that are required by the FOIA to be made available for public inspection in an electronic format may be accessed through the MCC website. MCC is responsible for determining which of its records are required to be made publicly available, identifying additional records in the interest of the public that are appropriate for public disclosure, and posting such records. MCC shall ensure that its website of posted records is reviewed and updated on an ongoing basis. The FOIA Program Officer may assist individuals in locating records on the MCC website and FOIA reading room.

§ 1304.4 Requirements for making requests.

(a) Requests for access to, or copies of, MCC records other than those identified in § 1304.3, shall be in writing and addressed to the MCC Chief FOIA Officer at 1099 14th St. NW, Washington, DC 20005 or FOIA@mcc.gov. All requests for records shall be deemed to have been made pursuant to the FOIA, regardless of whether the request specifically mentions the Freedom of Information Act. To facilitate processing, the requester should place the phrase "FOIA REQUEST" in capital letters on the front of the envelope or subject line of the email.

(b) Each request shall include the following:

(1) A description of the record(s) that provides sufficient detail to enable MCC to locate the record(s) with a reasonable amount of effort; such as the date, title or name, author, recipient, subject matter of the record, case number, file designation, or reference number. Before submitting their requests, requesters may contact the MCC FOIA Program Officer to discuss the records they are seeking and receive assistance in describing the records;

(2) The preferred format of the records;

(3) The requestor's full name, mailing address or email address, and telephone number where the requester can be reached during business hours; and

(4) If applicable, the maximum amount the requester is willing to pay or dollar limit on the fees MCC may incur to respond to the request for records. When this information is specified, MCC shall not exceed such limit.

(c) If a request does not meet all of the requirements of paragraph (b) of this section, the FOIA Program Officer may advise the requester that additional information is needed. Requesters who

are attempting to reformulate or modify a request may engage with the MCC Program Officer to clarify their request.

§ 1304.5 Responsibility for acknowledgment and initial determinations.

(a) Upon receipt of a request for records, the FOIA Program Officer will acknowledge receipt of the request in writing within ten (10) business days. In responding to a request for records, MCC shall make reasonable efforts to search for the records in electronic format, except when such efforts would significantly interfere with the operation of the agency's automated information system.

(b) The Chief FOIA Officer shall make an initial determination, within twenty (20) business days, to either grant or deny, in whole or in part, a request for records. If the Chief FOIA Officer shall notify the requester making such a request of the following information:

(1) The determination whether grant or deny the request and reasons for the determination;

(2) The right of the requester to seek assistance from the FOIA Public Liaison; and in the case of an adverse determination;

(3) The right of the requester to seek dispute resolution services via the Office of Government Information Services of the National Archives and Records Administration (OGIS); and

(4) The right to file an administrative appeal to the FOIA Appeals Officer within 90 calendar days after the date of the adverse determination.

§ 1304.6 Timing of responses to requests.

(a) *General information.* The twenty (20) business day period identified in § 1304.5(b) shall commence on the date that the request is first received by the MCC FOIA office and an acknowledgment of the request shall be sent no later than ten (10) business days after receipt of the request. The twenty (20) business day period shall not be tolled except that MCC may make one request to the requester for information and toll the twenty (20) business day period while it is awaiting receipt of the information, or the twenty (20) business day period may be tolled if it is necessary to clarify issues regarding fees with the requester.

(b) *Unusual circumstances.* If MCC cannot meet the statutory time limit for processing a request because of "unusual circumstances" as defined in the FOIA and MCC extends the time limit on that basis, MCC will, before expiration of the twenty (20) business day period, notify the requester in writing of the unusual circumstances involved and of the date by which MCC

estimates processing of the request will be completed. Where the extension exceeds ten (10) business days, MCC will provide the requester with an opportunity to modify the request or arrange an alternative time period for processing the original or modified request. MCC must make its designated FOIA Program Officer or FOIA Public Liaison available for this purpose. To aid the requester, the MCC FOIA Public Liaison shall assist in the resolution of any disputes between the requester and MCC, and notify the requester of the right to seek dispute resolution services from the Office of Government Information Services.

(c) *Aggregating requests.* MCC may aggregate requests where it reasonably appears that multiple requests, submitted either by a requester or by a group of requesters acting in concert, constitute a single request that would otherwise involve unusual circumstances. Requests that involve unrelated matters shall not be aggregated.

(d) *Multitrack processing.* MCC may use multitrack processing in responding to requests. This process entails separating simple requests that require rather limited review from more lengthy and complex requests. Requests in each track are then processed in their respective track. The FOIA Program Officer may provide requesters in the slower track an opportunity to limit the scope of their requests in order to decrease the processing time required. The FOIA Program Officer may provide the opportunity to limit the scope of the request by contacting the requester by letter, email, or telephone.

(e) *Expedited processing of requests.* The FOIA Program Officer must determine whether to grant a request for expedited processing within ten (10) calendar days of its receipt. Requests will receive expedited processing if one of the following criteria are met:

(1) The requester can establish that failure to receive the records quickly could reasonably be expected to pose an imminent threat to the life or physical safety of an individual;

(2) The requester is primarily engaged in disseminating information and can demonstrate that an urgency to inform the public concerning actual or alleged Federal Government activity exists; or

(3) As determined by the Chief FOIA Officer.

(f) *Written expedited requests.* A requester who seeks expedited processing must submit a written statement explaining in detail the basis for making the request for expedited processing. This statement must be certified to be true and correct. The

MCC Chief FOIA Officer may waive the formal certification requirement.

§ 1304.7 Responses to requests.

(a) *General information.* MCC, to the extent practicable, will communicate with requesters who have access to the internet via email or web portal.

(b) *Acknowledgment of requests.* MCC shall acknowledge the request in writing and assign a tracking number for processing purposes.

(c) *Estimated dates of completion and interim responses.* Upon request, MCC shall provide an estimated response date. If a request involves a voluminous amount of material or searches in multiple locations, MCC shall provide interim responses by releasing the records on a rolling basis.

(d) *Granting requests.* MCC will notify the requestor in writing if it determines that it will grant a request in full or in part. MCC shall inform the requester of any fees charged and shall disclose the requested records to the requester promptly upon payment of any applicable fees.

(e) *Partial grant of requests.* MCC shall consider whether partial disclosure of information is possible whenever the agency determines that a full disclosure of a requested record is not possible. MCC shall take reasonable steps necessary to segregate and release nonexempt information.

(f) *Denial or adverse determination of requests.* Except as otherwise provided in this part, MCC shall withhold information only if—

(1) It reasonably foresees that disclosure would harm an interest protected by an exemption under the FOIA or disclosure is prohibited by law;

(2) The request does not reasonably describe the records sought;

(3) The information sought is not a record subject to the FOIA;

(4) The information sought does not exist, cannot be located, or has been destroyed; or

(5) The records are not in the readily producible form or format sought by the requester.

(g) *Markings on released documents.* Records disclosed in part shall be marked clearly to show the amount of information deleted and the exemption under which the deletion was made unless doing so would harm an interest protected by an applicable exemption.

§ 1304.8 Confidential commercial information.

(a) *Designation of confidential commercial information.* A submitter of confidential commercial information must use good faith efforts to designate by appropriate markings, either at the

time of the submission or within a reasonable time thereafter, any portion of its submission that it considers to be protected from disclosure under Exemption 4 of the FOIA. These designations shall expire ten (10) years after the date of submission unless the submitter requests and provides justification for a longer designation period.

(b) *Required notice.* Written notice shall be provided to a submitter of confidential commercial information whenever records containing such information are requested under the FOIA if, after reviewing the request, the responsive records, and any appeal by the requester, it is determined that MCC may be required to disclose the records, provided:

(1) The requested information has been designated in good faith by the submitter as information considered protected from disclosure under Exemption 4 of the FOIA; or

(2) MCC has reason to believe that the requested information may be protected from disclosure under Exemption 4 of the FOIA, but has not yet determined whether the information is protected from disclosure under that exemption or any other applicable exemption.

(c) *Information.* The notices shall either describe the commercial information requested or include a copy of the requested records or portions of records containing information. In cases involving a voluminous number of submitters, notice may be made by posting or publishing the notice in a place or manner reasonably likely to accomplish it.

(d) *Exceptions to notice requirements.* The notices requirements of this section shall not apply if:

(1) The Chief FOIA Officer determines that the information is exempt under the FOIA;

(2) The information has been lawfully published or has officially been made available to the public;

(3) Disclosure of the information is required by a statute other than the FOIA or by a regulation issued in accordance with the requirements of Executive Order 12600 of June 23, 1987; or

(4) The designation made by the submitter under paragraph (b) of this section appears obviously frivolous, except that, in such a case, the component shall give the submitter written notice of any final decision to disclose the information and must provide that notice within a reasonable number of days prior to the disclosure date.

(e) *Opportunity to object to disclosure.* A submitter may provide the Chief

FOIA Officer with a detailed written statement of any objection to disclosure within ten (10) days of notification. The statement shall specify all grounds for withholding any of the information under any exemption of the FOIA, and if Exemption 4 applies, shall demonstrate the reasons the submitter believes the information to be confidential commercial information that is exempt from disclosure. Whenever possible, the submitter's claim of confidentiality shall be supported by a statement or certification by an officer or authorized representative of the submitter. In the event a submitter fails to respond to the notice in the time specified, the submitter will be considered to have no objection to the disclosure of the information. Information provided by the submitter that is received after the disclosure decision has been made will not be considered. Information provided by a submitter pursuant to this paragraph may itself be subject to disclosure under the FOIA.

(f) *Notice of intent to disclose.* The Chief FOIA Officer shall consider a submitter's objections and specific grounds for nondisclosure prior to determining whether to disclose the information requested. Whenever the Chief FOIA Officer determines that disclosure is appropriate, the Chief FOIA Officer shall, within a reasonable number of days prior to disclosure, provide the submitter with written notice of the intent to disclose which shall include a statement of the reasons for which the submitter's objections were overruled, a description of the information to be disclosed, and a specific disclosure date. The Chief FOIA Officer shall also notify the requester that the requested records will be made available.

(g) *Notice of lawsuit.* If the requester files a lawsuit seeking to compel disclosure of confidential commercial information, MCC shall promptly notify the submitter of this action. If a submitter files a lawsuit seeking to prevent disclosure of confidential commercial information, MCC shall promptly notify the requester.

§ 1304.9 Administrative appeals.

(a) *Requirements for appealing an adverse determination.* A requester may appeal any adverse determination to MCC. The requester must submit a written notice of appeal and it must be postmarked or, in the case of electronic submissions, transmitted within ninety (90) calendar days after the date of the response. The appeal should clearly identify the determination that is being appealed and the assigned tracking

number. To facilitate handling, the requester should mark both the appeal letter and envelope, or subject line of the electronic transmission, "Freedom of Information Act Appeal."

(b) *Appeals address.* Requesters can submit appeals by mail by addressing it to Millennium Challenge Corporation, Attn.: FOIA Appeals Officer, 1099 14th St. NW, Washington, DC 20005 or online at FOIA@mcc.gov.

(c) *Adjudication of appeals.* The MCC FOIA Appeals Officer will adjudicate the appeal within twenty (20) business days after the receipt of such appeal. An appeal ordinarily will not be adjudicated if the request becomes a matter of the subject of litigation. On receipt of any appeal involving classified information, the MCC FOIA Appeals Officer must take appropriate action to ensure compliance with applicable classification rules.

(d) *Final agency determinations.* The FOIA Appeals Officer shall issue a final written determination, stating the basis for the decision, within twenty (20) business days after receipt of a notice of appeal. Any decision that upholds MCC's determination in whole or in part must contain a statement that identifies the reason(s) for the decision, including any FOIA exemptions applied. The decision will provide the requester with notification of the statutory right to file a lawsuit and will inform the requester of the dispute resolution services offered by the OGIS of the National Archives and Records Administration as a non-exclusive alternative to litigation. If the Chief FOIA Officer's decision is remanded or modified on appeal, the FOIA Appeals Officer will notify the requester of the determination in writing. MCC will then further process the request in accordance with the appeal determination and will respond directly to the requester.

(e) *Engaging in dispute resolution services provided by OGIS.* Dispute resolution is a voluntary process. If MCC agrees to participate in the dispute resolution services provided by OGIS, MCC will actively engage as a partner to the process in an attempt to resolve the dispute.

(f) *When an appeal is required.* Before seeking review by a court of MCC's adverse determination, a requester generally must first submit a timely administrative appeal.

§ 1304.10 Preservation of records.

MCC shall preserve all correspondence pertaining to the requests that it receives under this part, as well as copies of all requested records, until disposition or destruction is authorized pursuant to Title 44 of the

United States Code or the General Records Schedule 4.2 of the National Archives and Records Administration. MCC shall not dispose of or destroy records while they are the subject of a pending request, appeal, or lawsuit under the FOIA.

§ 1304.11 Fees.

(a) *General information.* (1) MCC's fee provisions are governed by the FOIA and by the Office of Management and Budget's Uniform FOIA Fee Schedule and Guidelines. For purposes of assessing fees, the FOIA establishes the following categories of requesters:

- (i) Commercial use;
- (ii) Non-commercial scientific or educational institutions;
- (iii) Representative of the news media; and
- (iv) All other requesters.

(2) Fees will be assessed pursuant to the category of requester and detailed in paragraph (b) of this section. Requesters may seek a fee waiver. To resolve any fee issues that arise under this section, MCC may contact a requester for additional information. MCC will ensure that searches, review, and duplication are conducted in the most efficient and the least expensive manner. MCC ordinarily will collect all applicable fees before sending copies of records to a requester. Requesters must pay fees to the Treasury of the United States. All fee information is available at www.mcc.gov/resources/foia.

(b) *Charging fees.* Because the fee amounts provided already account for the direct costs associated with the given fee type, MCC will not add any additional costs to charges calculated under this section. In responding to FOIA requests, MCC shall charge fees for the following unless a waiver or reduction of fees has been granted:

(1) *Search time fees.* Search time includes page-by-page or line-by-line identification of information within records and the reasonable efforts expended to locate and retrieve information from electronic records.

(i) Requests made by education institutions, non-commercial scientific institutions, or representatives of the news media are not subject to search time fees. Search time fees shall be charged for all other requesters, subject to the restrictions identified in this section. MCC may properly charge for time spent searching even if no responsive records are located if it is determined that the records are entirely exempt from disclosure.

(ii) Requesters shall be charged the direct costs associated with conducting any searches that require the creation of a new computer program to locate the

requested records. Requesters shall be notified of the costs associated with creating such a program and must agree to pay the associated costs before the costs may be incurred.

(iii) For requests that require the retrieval of records stored by an agency at the Federal Records Centers operated by the National Archives and Records Administration (NARA), additional costs shall be charged in accordance with the Transactional Billing Range Schedule established by NARA.

(2) *Duplication fees.* Duplication fees shall be charged to all requesters, subject to the restrictions in this section. MCC shall honor a requester's preference for receiving a record in a particular form or format where it is readily reproducible by MCC in the form or format requested. Where photocopies are supplied, MCC shall provide one copy per request and charge fees calculated per page. For copies of records produced on tapes, disks, or other media, MCC shall charge the direct costs of producing the copy, including operator time. Where paper documents must be scanned in order to comply with a requester's preference to receive the records in an electronic format, the requester shall be charged direct costs associated with scanning those materials. For other forms of duplication, MCC shall charge the direct costs.

(3) *Review.* Review fees shall be charged to requesters who make commercial use requests. Review fees shall be assessed in connection with the initial review of the record. No charge will be made for review at the administrative appeal state of exemptions applied at the initial review stage. If a particular exemption is deemed to no longer apply, any costs associated with MCC's subsequent review following the administrative appeal of the records in order to consider the use of other exemptions may be assessed as review fees.

(c) *Restrictions on charging fees.* The following restrictions shall apply to MCC FOIA requests:

(1) If MCC fails to comply with the FOIA's time limits to respond to a request, MCC may not charge fees, except as described in paragraphs (c)(3) through (5) of this section;

(2) If MCC has determined that unusual circumstances as defined by the FOIA apply and the agency provided timely written notice to the requester in accordance with the FOIA, a failure to comply with the time limit shall be excused for an additional ten (10) calendar days;

(3) If MCC has determined that unusual circumstances as defined by the

FOIA apply, and more than five-thousand (5,000) pages are necessary to respond to the request, MCC may charge search time fees or duplication fees where applicable, if MCC has provided timely written notice of the unusual circumstances to the requester in accordance with the FOIA and has discussed with the requester via written mail, email, or telephone (or made a minimum of three (3) good-faith attempts to do so) how the requester could effectively limit the scope of the request;

(4) If a court has determined that exceptional circumstances exist as defined by the FOIA, a failure to comply with the time limits shall be excused for the length of time provided by the court order; and

(5) No search time or review fees will be charged for a quarter-hour period unless more than half of that period is required for search or review.

(d) *Fee exceptions.* Except for requesters seeking records for commercial use, MCC shall provide without charge:

(1) The first one-hundred (100) pages of duplication (or the cost equivalent for other media); and

(2) The first two (2) hours of search time. When, after deducting the first one-hundred (100) free pages (or its cost equivalent) and the first two (2) hours of search time, a total fee calculated under this section is \$25.00 or less for any request, no fee will be charged.

(e) *Notice of anticipated fees in excess of \$25.00.* (1) When MCC determines that the fees to be assessed will exceed \$25.00, the requester shall be notified of the actual or estimated amount of the fees, including the breakdown of the fees for search time, review or duplication, unless the requester has indicated a willingness to pay fees as high as those anticipated. If only a portion of the fee can be estimated readily, MCC shall advise the requester accordingly. If the requester is not a commercial use requester, the notice shall specify that the requester is entitled to the statutory requirements of one-hundred (100) pages of duplication at no charge and, if the requester is charged search time fees, two (2) hours of search time at no charge, and shall advise the requester whether those entitlements have been provided.

(2) In cases in which a requester has been notified that the actual or estimated fees are in excess of \$25.00, the request shall not be considered received and further work will not be completed until the requester commits, in writing, to pay the actual or estimated total fee, or designates some amount of fees the requester is willing to pay, or

in the case of a requester who is not a commercial use requester who has not yet been provided with the requester's statutory entitlements, designates that the requester seeks only that which can be provided by the statutory entitlements. The requester must provide the commitment or designation in writing, and must, when applicable designate an exact dollar amount the requester is willing to pay. MCC is not required to accept payments in installments.

(3) If the requester has indicated a willingness to pay some designated amount of fees, and MCC estimates that the total fee will exceed that amount, MCC shall toll the processing of the request when it notifies the requester of the estimated fees in excess of the amount the requester has indicated a willingness to pay. MCC shall inquire whether the requester wishes to revise the amount of fees the requester is willing to pay or modify the request. Once the requester responds, the time to respond will resume from where it was at the date of the notification.

(4) The FOIA Program Officer will assist any requester in reformulating a request to meet the requester's needs at a lower cost.

(f) *Waiver or reduction of fees.* Documents shall be furnished without charge or at a charge below that listed in this section based upon information provided by a requester or otherwise made known to the Chief FOIA Officer that disclosure of the requested information is in the public interest. Disclosure is in the public interest if it is likely to contribute significantly to public understanding of government operations and is not primarily for commercial purposes. Requests for a waiver or reduction of fees shall be considered on a case by case basis. Where only some of the records to be released satisfy the requirements for waiver of fees, a waiver shall be granted to those records. In order to determine whether the fee waiver requirement is met, the Chief FOIA Officer shall consider the following factors:

(1) The subject of the request. Whether the subject of the requested records concerns the operations or activities of the government;

(2) The informative value of the information to be disclosed; and

(3) The significance of the contribution to public understanding.

(g) *Fees pending a waiver request.* Requests for a waiver or reduction of fees should be made when the request is first submitted to the agency and should address the criteria referenced in this section. A requester may submit a fee waiver request at a later time so long

as the underlying record request is pending or on administrative appeal. When a requester who has committed to pay fees subsequently asks for a waiver of those fees and that waiver is denied, the requester must pay any costs incurred up to the date the fee waiver request was received.

(h) *Types of requesters.* There are four categories of FOIA requesters: Commercial use requesters, educational and non-commercial scientific institutional requesters; representatives of the news media; and all other requesters. The following specific levels of fees are prescribed for each of these categories:

(1) Commercial requesters shall be charged the full direct costs of searching for, reviewing, and duplicating requested records;

(2) Educational and non-commercial scientific institution requesters shall be charged for document duplication only and the first one-hundred (100) pages of paper copies shall be provided without charge;

(3) Representative of the news media requesters shall be charged for document duplication costs only, except that the first one-hundred (100) pages of paper copies shall be provided without charge; and

(4) All other requesters who do not fall into any of the categories in paragraphs (h)(1) through (3) of this section shall be charged fees which recover the full reasonable direct costs incurred for searching for and reproducing records if that total costs exceeds \$25.00, except that the first one-hundred (100) pages of duplication and the first two hours of manual search time shall not be charged.

(i) *Charges for unsuccessful searches.* If the requester has been notified of the estimated cost of the search time and has been advised specifically that the requested records may not exist or may be withheld as exempt, fees may be charged.

(j) *Charges for other services.* Although MCC is not required to provide special services, if it chooses to do so as a matter of administrative discretion, the direct costs of providing the service shall be charged. Examples of such services include certifying that records are true copies, providing multiple copies of the same document, or sending records by means other than first class mail.

(k) *Charging interest.* MCC may charge interest on any unpaid bill starting on the 31st day following the date of billing the requester. Interest charges shall be assessed at the rate provided in 31 U.S.C. 3717 and will accrue from the billing date until payment is received.

MCC shall follow the provisions of the Debt Collection Act of 1982, as amended, and its administrative procedures, including the use consumer reporting agencies, collection agencies, and offset.

(l) *Aggregating requests.* The requester or a group of requesters may not submit multiple requests at the same time, each seeking portions of a document or documents solely in order to avoid payment of fees. When the FOIA Program Officer reasonably believes that a requester is attempting to divide a request into a series of requests to evade an assessment of fees, the FOIA Program Officer may aggregate such requests and charge accordingly. MCC may presume that multiple requests of this type made within a thirty (30) calendar day period have been made in order to avoid fees. For requests separated by a longer period, MCC will aggregate them only where there is a reasonable basis for determining that aggregation is warranted in view of all the circumstances involved. Multiple requests involving unrelated matters cannot be aggregated.

(m) *Advance payment of fees.* (1) MCC may require an advanced payment of fees if the requestor previously failed to pay fees or if the FOIA Program Officer determines the total fee will exceed \$250.00. When payment is required in advance of the processing of a request, the time limits prescribed in § 1304.5 shall not be deemed to begin until the requester has paid the assessed fees.

(2) In cases in which MCC requires advance payment, the request will not be considered received and further work will not be completed until the required payment is received. If the requester does not pay the advance payment within thirty (30) calendar days after the date of the fee determination, the request will be closed. Where it is anticipated that the cost of providing the requested record will exceed \$25.00 but falls below \$250.00 after the free duplication and search time has been calculated, MCC may, in its discretion may require either an advance deposit of the entire estimated charges or written confirmation of the requester's willingness to pay such charges.

(3) Where the requester has previously failed to pay a properly charged FOIA fee within thirty (30) calendar days of the billing date, MCC may require the requester to pay the full amount due plus any applicable interest on that prior request, and/or require that the requester make an advance payment of the full amount of the anticipated fee before MCC begins a new request or

continues to process a pending request or any pending appeal. If MCC has a reasonable basis to believe that a requester has misrepresented the requester's identity in order to avoid paying outstanding fees, MCC may require that the requester provide proof of identity.

§ 1304.12 Other rights and services.

Nothing in this part shall be construed to entitle any person a right to any service or to the disclosure of any record to which such person is not entitled under the FOIA.

Dated: July 17, 2018.

Tamiko N.W. Watkins,
Chief FOIA Officer, Millennium Challenge Corporation.

[FR Doc. 2018-15950 Filed 7-26-18; 8:45 am]

BILLING CODE 9211-03-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2018-0660]

Drawbridge Operation Regulation; Jamaica Bay, Queens, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Marine Parkway (Gil Hodges Memorial) bridge across Jamaica Bay (Rockaway Inlet), mile 3.0, at Queens, NY. The deviation is necessary to complete rehabilitation work on the bridge. This deviation allows the bridge owner to require two hours advance notice before opening the bridge.

DATES: This deviation is effective from 8 a.m. on July 30, 2018, to 4 p.m. on November 30, 2018.

ADDRESSES: The docket for this deviation, USCG-2018-0660 is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Judy Leung-Yee, Bridge Management Specialist, First District Bridge Branch, U.S. Coast Guard; telephone 212-514-4336, email Judy.K.Leung-Yee@uscg.mil.

SUPPLEMENTARY INFORMATION: The owner of the bridge, Metropolitan Transportation Authority Bridges and Tunnels, requested a temporary deviation from the normal operating schedule in order to complete rehabilitation work associated with the replacement of lift span machinery. The Marine Parkway (Gil Hodges Memorial) Bridge across Jamaica Bay (Rockaway Inlet), mile 3.0 at Queens, New York has a vertical clearance of 55 feet at mean high water and 59 feet at mean low water in the closed position. The existing drawbridge operating regulations are listed at 33 CFR 117.795(a).

The temporary deviation will allow the owner of the Marine Parkway (Gil Hodges Memorial) bridge to require vessels seeking an opening of the draw to provide a minimum of two hours of advance notice on weekdays (Monday through Friday) between the hours of 8 a.m. and 4 p.m. from July 30, 2018 to November 30, 2018 by submitting a request for the opening of the draw. Requiring a minimum of two hours of advance notice before opening the draw allows for sufficient time to alert all affected personnel engaged in bridge rehabilitation work to vacate the lift span and all machinery areas along, with removing and/or securing materials and equipment prior to lifting the bridge.

The waterway is transited by seasonal recreational traffic as well as commercial vessels, largely tug and barge combinations. The 55 foot vertical clearance while the bridge is in the closed position offers the bulk of commercial traffic sufficient room to transit under the bridge in the closed position. Vessels that can pass under the bridge without an opening may do so at all times. The bridge will be able to open for emergencies. There is no immediate alternate route for vessels unable to pass through the bridge when in the closed position.

The Coast Guard will inform users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by this temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 23, 2018.

C.J. Bisignano,

*Supervisory Bridge Management Specialist,
First Coast Guard District.*

[FR Doc. 2018–16026 Filed 7–26–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0701]

Drawbridge Operation Regulation; Willamette River at Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from
drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs two Multnomah County bridges: Morrison Bridge, mile 12.8, and Hawthorne Bridge, mile 13.1 crossing the Willamette River at Portland, OR. This deviation is necessary to accommodate the annual Providence Bridge Pedal event. The deviation allows the bridges to remain in the closed-to-navigation position.

DATES: This deviation is effective from 6 a.m. to 11 a.m. on August 12, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0701 is available at <http://www.regulations.gov>. Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email d13-pf-d13bridges@uscg.mil.

SUPPLEMENTARY INFORMATION: Multnomah County, the bridge owner, has requested a temporary deviation from the operating schedule for the Morrison Bridge, mile 12.8, and Hawthorne Bridge, mile 13.1, both crossing the Willamette River at Portland, OR. The requested deviation will accommodate the Providence Bridge Pedal event, an annual cycling and walking event across several Willamette River crossings. The vertical clearances for these bridges in the closed-to-navigation position are 69 feet for the Morrison Bridge and 49 feet for the Hawthorne Bridge respectively, as measured against the vertical clearance above Columbia River Datum 0.0. The

normal operating schedule for the subject bridges is 33 CFR 117.897. This deviation allows the Morrison Bridge and Hawthorne Bridge to remain in the closed-to-navigation position, from 6 a.m. to 11 a.m. on August 12, 2018.

Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. Vessels able to pass through the subject bridges in the closed-to-navigation position may do so at any time. The bridges will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard has conducted public outreach regarding this temporary deviation to known mariners that transit this part of the river. The Coast Guard has not received any objections to this temporary deviation from the operating schedule. The Coast Guard will inform the users of the waterway, through our Local and Broadcast Notices to Mariners, of the change in operating schedule for the bridges so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedules immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 23, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–16068 Filed 7–26–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0708]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, Natchez, MS

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Lower Mississippi River upriver of the Bienville Trace Scenic Byway/US–425 Bridge in Natchez, MS. This action is necessary to provide for the safety of persons, vessels, and the marine environment during a fireworks display.

Entry of persons or vessels into this zone is prohibited unless authorized by the Captain of the Port Sector Lower Mississippi River or a designated representative.

DATES: This rule is effective from 9 p.m. through 10 p.m. on July 27, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2018–0708 in the “SEARCH” box and click “SEARCH.” Click on “Open Docket Folder” on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Petty Officer Todd Manow, Waterways Management, Sector Lower Mississippi River, U.S. Coast Guard; telephone 901–521–4813, email Todd.M.Manow@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Lower
Mississippi River
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency, for good cause, finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this safety zone by July 27, 2018, and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule. The NPRM process would delay the establishment of the safety zone until after the date of the event and compromise public safety.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to public interest because immediate action is necessary to protect

persons and property from the potential hazards associated with the fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority in 33 U.S.C. 1231. The Captain of the Port Sector Lower Mississippi River (COTP) has determined that potential hazards associated with the barge-based fireworks display located at mile marker (MM) 365.0 on the Lower Mississippi River and scheduled for 9:30 p.m. on July 27, 2018, would be a safety concern for all persons and vessels on the Lower Mississippi River between MM 364.5 and MM 365.5 from 9 p.m. through 10 p.m. on July 27, 2018. Hazards associated with the firework displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. This rule is necessary to ensure the safety of persons, vessels, and the marine environment on these navigable waters before, during, and after the fireworks.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 9 p.m. through 10 p.m. on July 27, 2018. The safety zone will cover all navigable waters of the Lower Mississippi River from MM 364.5 to MM 365.5, upriver of the Bienville Trace Scenic Byway/US-425 Bridge, in Natchez, MS. The duration of this safety zone is intended to ensure the safety of waterway users on these navigable waters before, during, and after the scheduled fireworks display.

Entry of persons or vessels into this safety zone is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Lower Mississippi River. Persons or vessels seeking to enter the safety zones must request permission from the COTP or a designated representative on VHF-FM channel 16 or by telephone at 901-521-4822. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative. The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and

Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget, and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be prohibited from entering this safety zone, which will impact a one-mile stretch of lower Mississippi River for one hour on one evening. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF-FM marine channel 16 about the safety zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

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

listed in the **FOR FURTHER INFORMATION CONTACT** section.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule

will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will prohibit entry on a one-mile stretch of the Lower Mississippi River for one hour on one evening. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05-1; 6.04-1, 6.04-6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.T08-0708 to read as follows:

§ 165.T08-0708 Safety Zone; Lower Mississippi River, Natchez, LA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Lower Mississippi River from mile marker 364.5 to mile marker 365.5,

upriver of the Bienville Trace Scenic Byway/US-425 Bridge, Natchez, MS.

(b) *Effective date.* This section is effective from 9 p.m. through 10 p.m. on July 27, 2018.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Lower Mississippi River (COTP) or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Lower Mississippi River.

(2) Persons or vessels seeking to enter the safety zone must request permission from the COTP or a designated representative on VHF-FM channel 16 or by telephone at 901-521-4822.

(3) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

Dated: July 20, 2018.

R. Tamez,

Captain, U.S. Coast Guard, Captain of the Port Sector Lower Mississippi River.

[FR Doc. 2018-16076 Filed 7-26-18; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2018-0686]

RIN 1625-AA00

Safety Zone; Kanawha River, Nitro, WV

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Kanawha River from mile marker 43.1 to mile marker 44.2. This temporary safety zone is necessary to protect persons, vessels, and the marine environment from potential hazards associated with the Riverfest fireworks display. Entry into this safety zone is prohibited unless specifically authorized by the Captain of

the Port Sector Ohio Valley or a designated representative.

DATES: This rule is effective from 8:45 p.m. through 10:15 p.m. on August 4, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2018-0686 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Caitlin Furman, Marine Safety Unit Huntington, U.S. Coast Guard; telephone 304-733-0198, email caitlin.c.furman@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Ohio Valley
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. It is impracticable to publish an NPRM because we must establish this safety zone by August 4, 2018, and we lack sufficient time to provide reasonable comment period and then consider those comments before issuing the rule. The NPRM process would delay the establishment of the safety zone until after the date of the event and compromise public safety.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to public interest because immediate action is necessary to protect persons, vessels, and the marine

environment from the potential hazards associated with the fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with a fireworks display taking place over this section of the Kanawha River will be a safety concern for anyone within a one-mile stretch of the waterway. This rule is needed to protect persons, vessels, and the marine environment in the navigable waters within the safety zone before, during, and after the scheduled fireworks display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone for the Riverfest fireworks display from 8:45 p.m. until 10:15 p.m. on August 4, 2018. The safety zone covers all navigable waters of the Kanawha River from mile marker (MM) 43.1 to MM 44.2, in Nitro, WV. The duration of this safety zone is intended to protect persons, vessels, and the marine environment in these navigable waters during the fireworks display.

No vessel or person is permitted to enter this safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Ohio Valley. To seek permission to enter, contact the COTP or designated representative via radio on channel 16 or by telephone at 1-800-253-7465. If permission is granted, all persons and vessels shall transit at their slowest safe speed and comply with the instructions of the COTP or designated representative. The COTP or a designated representative will inform the public of any changes in the date and times of enforcement through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Safety Marine Information Broadcasts (SMIBs), as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory

alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the temporary safety zone. This rule involves a temporary safety zone lasting only one hour and thirty minutes that will prohibit entry on a one-mile stretch of the Kanawha River on one evening. Moreover, the Coast Guard will issue a BNMs via VHF-FM marine channel 16 about the safety zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

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

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business

Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant

Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only one hour and thirty minutes that will prohibit entry on a one-mile stretch of the Kanawha River on one evening. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0686 to read as follows:

§ 165.T08–0686 Safety Zone; Kanawha River, Nitro, WV.

(a) *Location.* The following area is a safety zone: All navigable waters of the Kanawha River from mile marker (MM) 43.1 to MM 44.2.

(b) *Effective period.* This section is effective from 8:45 p.m. through 10:15 p.m. on August 4, 2018.

(c) *Regulations.* (1) Under the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port Sector Ohio Valley (COTP) or a designated representative. A designated

representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Ohio Valley.

(2) To seek permission to enter, contact the COTP or designated representative via radio on channel 16 or by telephone at 1–800–253–7465.

(3) If permission is granted, all persons and vessels shall transit at their slowest safe speed and comply with the instructions of the COTP or designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of any changes in the date and times of enforcement through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Safety Marine Information Broadcasts (SMIBs), as appropriate.

Dated: July 18, 2018.

M.B. Zamperini,

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

[FR Doc. 2018–16064 Filed 7–26–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2008–0084; FRL–9981–36—Region 6]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Old Esco Manufacturing Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 6 is publishing a direct final Notice of Deletion of the Old Esco Manufacturing, Superfund Site (Site), located in Greenville, Texas, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Texas, through the Texas Commission on Environmental Quality (TCEQ), because EPA has determined that all appropriate response actions under CERCLA, have been completed.

However, this deletion does not preclude future actions under Superfund.

DATES: This direct final deletion is effective September 10, 2018 unless EPA receives adverse comments by August 27, 2018. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–2008–0084, by one of the following methods:

- <http://www.regulations.gov>. Follow on-line instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

- *Email:* mueller.brian@epa.gov.
- *Mail:* Brian W. Mueller; U.S.

Environmental Protection Agency, Region 6; Superfund Division (6SF–RL); 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

- *Hand delivery:* U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733; Contact: Brian W. Mueller (214) 665–7167. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SFUND–2008–0084. The <http://www.regulations.gov> website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without

going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at:

City of Greenville Municipal Bldg., 2821 Washington Street, Greenville, TX 75401, Telephone Number: (903) 457-3130, Hours of Operation: Monday thru Friday 8:00 a.m. to 5:00 p.m.

U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 1200, Dallas, TX 75202-2733, Telephone number: (800) 533-3508, Contact: Brian W. Mueller, (214) 665-7167, Hours of operation: Monday thru Friday, 9:00 a.m. to 12:00 p.m. and 1:00 p.m. to 4:00 p.m.

Texas Commission on Environmental Quality, Records Management Center, Central File Room, Technical Park Center Bld. E, 1st Floor, Room 1003, 12100 Park 35 Circle, Austin, TX 78753, Telephone Numbers: (512) 239-2900 and (800) 633-9363, Hours of operation: Monday thru Friday, 8:00 a.m. to 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Brian W. Mueller, Remedial Project Manager, U.S. Environmental Protection Agency, Region 6, 6SF-RL 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202-2733, (214) 665-7167, email mueller.brian@epa.gov.

SUPPLEMENTARY INFORMATION:

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- I. Introduction
- II. NPL Deletion Criteria
- III. Deletion Procedures
- IV. Basis for Site Deletion

V. Deletion Action

I. Introduction

EPA Region 6 is publishing this direct final Notice of Deletion of the Old Esco Manufacturing (Site), from the National Priorities List (NPL). The NPL constitutes Appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in § 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for Fund-financed remedial actions if future conditions warrant such actions.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Old Esco Manufacturing Superfund Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the state, whether any of the following criteria have been met:

- i. Responsible parties or other persons have implemented all appropriate response actions required;
- ii. all appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or
- iii. the remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

III. Deletion Procedures

The following procedures apply to deletion of the Site:

- (1) EPA consulted with the State of Texas prior to developing this direct final Notice of Deletion and the Notice

of Intent to Delete co-published today in the "Proposed Rules" section of the **Federal Register**.

(2) EPA has provided the state 30 working days for review of this notice and the parallel Notice of Intent to Delete prior to their publication today, and the state, through the Texas Commission on Environmental Quality, has concurred on the deletion of the Site from the NPL.

(3) Concurrently with the publication of this direct final Notice of Deletion, a notice of the availability of the parallel Notice of Intent to Delete is being published in a major local newspaper, Greenville Herald Banner. The newspaper notice announces the 30-day public comment period concerning the Notice of Intent to Delete the Site from the NPL.

(4) The EPA placed copies of documents supporting the proposed deletion in the deletion docket and made these items available for public inspection and copying at the Site information repositories identified above.

(5) If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely notice of withdrawal of this direct final Notice of Deletion before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments already received.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Site Deletion

The following information provides EPA's rationale for deleting the Site from the NPL:

Site Background and History

The Old Esco Manufacturing ("Old Esco" or "site") Superfund Site (CERCLIS ID TXD980573808) is located at 500 Forrester Street, Greenville, Hunt County, Texas. The geographic coordinates of the Site are Latitude 33.138732° N and Longitude -96.075961° W. The facility, which is currently abandoned, is situated on a

4.7-acre tract of land owned by the City of Greenville.

The boundaries of the Site are surrounded by fencing. The Site is bordered to the north by Forrester Street, to the east by a residential area and vacant lot, to the south by the frontage road of Interstate 30 and a drainage pathway to Horse Creek and the Cowleech Fork of the Sabine River, and to the west by a private lake. The Site consisted of several attached buildings that form one main building (125 by 500 feet), a small shed (15 by 20 feet), and vacant land. A former soil and gravel parking lot is located on the north and west sides of the building.

Esco began operations at the Site in the late 1940s, leasing the property and building, until approximately 1970, when the company relocated to another property in Greenville, Texas. In 1983, Esco purchased the Site and owned it until it defaulted for non-payment of taxes in 2001. Esco manufactured electrical transformers and high voltage switchgear for electrical distribution at the Site. Other manufacturing operations at the Site included metal fabrication, welding, grinding, sandblasting, silver electroplating, and painting. Completed transformers from the facility were either shipped dry (*i.e.*, empty of coolant) or were filled with polychlorinated biphenyl (PCB) dielectric oil, depending on the requirements of the purchaser.

PCBs are mixtures of synthetic organic chemicals that were commonly used for various applications from approximately 1929 until 1979. PCBs were regulated under a series of EPA actions culminating with a ban in 1979 on manufacturing, processing, distribution, and use of PCBs under the Toxic Substances Control Act (TSCA). Items such as transformers and hydraulic fluids were identified as high-risk sources and were targeted for accelerated phase-out.

In July 1980, the Texas Department of Water Resources (TDWR) received a complaint about the historic disposal of transformer oil by Esco on the property. The investigation by TDWR revealed the presence of PCBs at concentrations of 760, 8,400, and 85,000 milligrams per kilogram (mg/kg) in the soils. In April 1981, the TDWR recommended that Esco conduct an extent-of-contamination survey within 180 days and develop a removal plan that would eliminate the PCB-contaminated soil from the Site. In 1990, Esco filed for Chapter 11 Bankruptcy without conducting the cleanup. In 1991, the Chapter 11 bankruptcy was converted to a Chapter 7 bankruptcy. In 2003, the (TCEQ) conducted a Phase I & II

Environmental Site Assessment, and installed one new monitoring well and collected 23 surface and subsurface soil samples. Chemical analysis of the surface soil samples indicated the presence of the PCB, Aroclor-1260 in concentrations ranging from 0.338 to 2,390 mg/kg. Chemical analysis of the subsurface soil samples indicated the presence of Aroclor-1260 at a concentration of 12.2 mg/kg. Ground water was encountered at approximately 10 to 15 feet below ground surface (bgs). Chemical analysis of the ground water samples collected from two monitoring wells indicated the presence of Aroclor-1260.

In 2004, the TCEQ formally referred the Site to EPA Region 6 for assistance. From 2005 through 2007, EPA's removal program conducted numerous field sampling and assessment activities at the Site and adjacent properties to determine the extent of contamination and for National Priorities List (NPL) Hazard Ranking System scoring purposes. The Site was proposed to the NPL on March 19, 2008, (73 FR 14742). The Site was added to the NPL as final on September 3, 2008, (73 FR 51368).

History of EPA CERCLA Removal Actions

EPA conducted two Time Critical Removal Actions which began in August 2008 and September 2009, respectively. The purpose of these Removal Actions was to investigate the PCB-contaminated soils in the residential and other adjacent areas of the Site; and to eliminate the imminent threat and substantial endangerment to public health or welfare, or to the environment, posed by site-related contamination associated with the Old Esco Manufacturing Site. Based on removal assessment activities conducted by EPA, the Old Esco Manufacturing Site and surrounding residential properties were found to contain elevated levels of PCBs above the EPA Toxic Substances Control Act (TSCA) screening level of 1 milligram per kilogram (mg/kg).

First Removal Action

The first of these two Removal Actions was completed in January 2009. This Removal Action included:

- Removal of PCB-contaminated soils with a concentration greater than 1.0 mg/kg from six adjacent residential properties and the adjacent Texas Department of Transportation road right-of-way drainage ditches located directly east of the Site.
- Restoration of the six residential properties and roadside ditches.

- Transportation and disposal of 922 tons of soils in the CSC Landfill in Avalon, Texas with concentrations of PCBs equal to or greater than 50.0 mg/kg (TSCA soils) and 4,221 tons of soils in the Maloy Landfill near Campbell, Texas with concentrations of PCBs less than 50.0 mg/kg (Non-TSCA soils).

- On-site consolidation and storage of approximately 4,000 cubic yards (yd³) of TSCA soils in the building.

- Fencing of the perimeter of the Esco property.

- Removal and disposal of 120 yd³ of asbestos-containing materials from the on-site building in the Maloy Landfill.

- Placement of ripple dams/storm water controls in drainage pathways between residential properties and the Site to reduce the potential for contaminated soil backflow onto clean areas during flooding situations.

- Placement of ripple dams at several locations on the Esco drainage system to reduce off-site soil migration.

Second Removal Action

The second Removal Action was completed in December 2009. This Removal Action included:

- Removal of soils with concentrations of PCBs greater than 1.0 mg/kg from three residential properties and portions of the road side drainage ditches along Fannin and Forrester Streets.

- Restoration of the three residential properties and the road side drainage ditches.

- Transportation and disposal of approximately 3,194 tons of soils in the Maloy Landfill with concentrations of PCBs less than 50.0 mg/kg (Non-TSCA soils).

Remedial Investigation and Feasibility Study (RI/FS)

In 2009, EPA's remedial program started and completed the off-site Remedial Investigation (RI) and extent of contamination study by collecting soil samples for PCB analysis from an additional 52 residential properties, and from Texas Department of Transportation highway median and road right-of-way drainage ditches that had not been previously sampled. The RI also included the collection of twelve co-located water and sediment samples from Horse Creek and the Cowleech Fork of the Sabine River, and the collection of ground water samples for PCB analyses.

In 2010, EPA's remedial program completed the full RI/FS. Surface and subsurface soil samples were collected from the on-site areas of the Site to determine the nature and extent of contamination. Sampling results

showed that soils as deep as 10.0 feet below ground surface were impacted by PCBs and required remediation. TSCA PCB regulations applied to the Site because surface and subsurface soils were contaminated by PCBs. The concentrations of PCBs required that the contaminated soils be managed as non-TSCA (*i.e.*, concentration less than 50.0 mg/l total PCBs) or TSCA wastes (*i.e.*, concentration equal to or greater than 50.0 mg/kg total PCBs).

Ground water samples were collected from the on-site monitoring wells to determine the nature and extent of contamination in the ground water underlying the Site. The primary ground water contaminants were PCBs and the extent of ground water impact was limited. A total of nine monitoring wells were installed on the Site. Five were installed and sampled prior to the Site being listed on the NPL. In 2003 the wells were sampled and the results indicated that the PCB Aroclor-1260 was present in the ground water in two monitoring wells at concentrations ranging from 9.26 to 0.379 micrograms per liter ($\mu\text{g/L}$). In 2009 the wells were resampled and the same two wells reported PCB results of 1.1 and 1.5 $\mu\text{g/L}$, both above the Maximum Contaminant Level (MCL) of 0.5 $\mu\text{g/L}$.

In 2010, four additional wells were installed by EPA's contractor. Nine ground water samples were collected for PCB analysis in 2010. The ground water chemical analytical data collected indicated that only Aroclor-1260 was detected in four wells ranging from 0.04 to 0.46 $\mu\text{g/L}$, which were below the MCL of 0.5 $\mu\text{g/L}$.

Surface water samples were collected from Horse Creek and the Cowleech Fork of the Sabine River to determine the nature and extent of surface water contamination. No Aroclors were detected at the appropriate detection limits and no further action was recommended for surface water.

Sediment data were collected from Horse Creek and the Cowleech Fork of the Sabine River to determine the nature and extent of sediment contamination. Although the maximum sediment concentrations for Aroclor-1268 and Aroclor-1260 were above the screening benchmark for sediments, the screening level ecological risk assessment findings indicated that no further action was required for sediments.

Remedial Action Objectives

The Remedial Action Objectives to be achieved by the Site Remedy were:

- Prevent direct dermal contact, incidental ingestion and inhalation of fugitive dust from PCB-contaminated soils,

- Prevent off-site migration of PCB-contaminated soils to Horse Creek or the Cowleech Fork of the Sabine River,

- Prevent exposure to Site soils that may pose a risk to ecological receptors, and

- Ensure that current and future receptors were not exposed to ground water that could possibly be contaminated with PCBs above the federal MCL of 0.5 $\mu\text{g/L}$.

Remedial Action Goals

The excavation, on-site treatment, and off-site disposal of the soils with a concentration of total PCBs greater than 1.0 mg/kg would allow the Site to be developed for reuse (*i.e.*, residential and/or recreational and commercial and/or industrial land use). The remediation goal for total PCBs for the Site was 1.0 mg/kg.

Selected Remedy

The selected remedy for the Site, as described in the original 2010 Record of Decision (ROD), was Soil Excavation and Treatment with Off-site Disposal for Residential and/or Recreational Land Use, and included the following major components:

- Soil Excavation, Treatment, and Disposal Components: Approximately 5,200 and 16,250 yd^3 of TSCA and non-TSCA soils, respectively, with a concentration of total PCBs greater than 1.0 milligrams per kilogram (mg/kg) were to be excavated and transported off-site to a permitted waste disposal facility. Soils were to be excavated to a maximum depth of 15.0 bgs, consistent with the State's requirements. Soils with a concentration of total PCBs equal to or greater than 50.0 mg/kg were to be disposed of at a TSCA-permitted landfill. Soils with a concentration of total PCBs greater than 1.0 mg/kg and less than 50.0 mg/kg were to be disposed of at a non-TSCA landfill. Approximately 1,850 yd^3 of soils with a concentration of total PCBs greater than 100.0 mg/kg, constituting principal threat wastes, were to be treated on-site by solidification or stabilization techniques prior to disposal.

Approximately 4,000 yd^3 of TSCA soils, with a concentration of total PCBs less than 100.0 mg/kg, staged in the existing building from EPA's first removal action, were also to be transported off-site for disposal. Excavated areas were to be backfilled with clean off-site soils and the Site was to be graded to drain and not pond water. The existing building and its foundation were to be demolished and also transported off-site for disposal.

- Institutional Controls Component—Institutional Controls (ICs), in the form

of deed restrictions, were to be implemented to prevent exposure of human receptors to contaminated ground water.

- Ground Water Monitoring Component—Ground water monitoring was to be conducted annually for a minimum period of five years to evaluate the protectiveness of the Selected Remedy. Ground water monitoring was to be discontinued if the concentration of total PCBs in the ground water did not exceed the federal MCL of 0.5 $\mu\text{g/L}$ for three consecutive monitoring periods. The additional data collected during the annual monitoring events was to be used to confirm previous PCB data and further evaluate trends over time. The additional monitoring data was to also allow decisions to be made in the future regarding ground water impacts and evaluation of risks to human health, the need for additional monitoring, whether to continue maintaining ICs, and whether any additional actions would be needed to protect human health and the environment. These decisions were to be made during the first five-year review report for the Site.

- Operations and Maintenance Component—Operations and maintenance was to involve the ground water component of the remedy to ensure that the remedy performed as intended.

- Five-Year Review Component—Because this alternative would result in hazardous substances (*i.e.*, PCBs) remaining on-site in the ground water, possibly above levels that allow for unlimited use and unrestricted exposure, a statutory review was to be conducted no less often than every five years after initiation of the RA to ensure that the remedy was, or will continue to be, protective of human health and the environment. Five-year reviews were to be discontinued if the ground water monitoring data indicate that the concentration of total PCBs did not exceed the federal MCL of 0.5 $\mu\text{g/L}$ for three consecutive monitoring periods.

Third Removal Action

On May 4, 2011, EPA signed a Third Action Memorandum, which documented the continuation of the Time Critical Removal Action and approval of the Consistency Exemption for the Site. The Consistency Exemption documented that the continued response actions were appropriate and consistent with the 2010 ROD selected remedy and remedial actions.

The Third Removal Action was completed with issuance of the final Pollution Report #10 on September 30, 2011. Between May 24 and September

12, 2011, all PCB-contaminated soils were excavated and transported off-site to permitted disposal facilities, and the existing building and foundation was demolished and also transported off-site for disposal. A total of 28,288 tons of Non-TSCA soils, 24,137 tons of TSCA PCB-contaminated soils, 343 tons of construction debris, and 1,455 tons of non-TSCA PCB-contaminated Class II concrete were transported off-site for disposal. The TSCA soils were disposed of at the CSC Landfill and the non-TSCA soils, construction debris, and non-TSCA PCB Class II concrete were disposed of at the Maloy Landfill. Following confirmation that all PCB-contaminated had been removed, excavated areas were backfilled with approximately 60,000 yd³ of clean off-site soils and the Site was graded so that it would drain and prevent the formation of standing water.

No Further Action Is Necessary Record of Decision Amendment and Explanation of Significant Differences (2011)

The No Further Action is Necessary Record of Decision Amendment and Explanation of Significant Differences (ROD Amendment) was signed on September 28, 2011. The ROD Amendment was prepared to document EPA's implementation and completion of the post-ROD Third Removal Action for the PCB-contaminated soils at the Site. The completion of the soil clean up, which utilized the selected remedy in the original 2010 ROD, eliminated the need to conduct further soil remedial actions at the Site. The Explanation of Significant Differences (ESD) portion of the ROD Amendment presented the details of non-significant or minor changes to the July 2011 Proposed Plan. After the 2011 Proposed Plan was proposed to the public, but before the ROD Amendment was finalized, EPA received the 2011 annual ground water monitoring data, which showed that all concentrations for total PCBs did not exceed the federal MCL of 0.5 µg/L. As a result, EPA determined that changes to the 2011 Proposed Plan were necessary, and the ESD documented those changes. The changes would not have a significant impact on the scope, performance or cost of the remedy.

- The 2011 Proposed Plan stated that ground water monitoring was to be conducted annually for a minimum of five years to evaluate the protectiveness of the proposed remedy. Ground water monitoring was to be discontinued if the concentration of total PCBs in ground water did not exceed the federal MCL of 0.5 µg/L for three consecutive monitoring periods. The ESD added to

the Ground Water Monitoring Component that PCB concentrations had already been below the MCL for two (2010 and 2011) consecutive monitoring periods and that if the PCB levels were below the MCL in the third round of ground water sampling scheduled for 2012, ground water monitoring would be discontinued.

- Institutional controls in the form of deed restrictions were to be implemented to prevent exposure of human receptors to contaminated ground water. The ESD stated that these institutional controls would not be implemented at the Site because the 2010 and 2011 monitoring results for PCBs were below the MCL.

- The ESD eliminated the Operations and Maintenance of the ground water component of the remedy after ground water monitoring was to be discontinued.

- Five-Year Reviews would be discontinued if the ground water data indicated that the concentration of total PCBs did not exceed the federal MCL of 0.5 µg/L.

Cleanup Levels

Soils

As stated above, during the Third Removal Action all PCB-contaminated soils were excavated and transported off-site to permitted disposal facilities. The Removal Action was completed by September 2011. After the Removal Action was completed, EPA collected post-construction confirmation soil samples from the bottom of the 52 excavated grids to verify that all PCB-contaminated soils above the total PCB cleanup level of 1.00 mg/kg had been removed. All soil samples were reported below the 1.00 mg/kg cleanup level.

Ground Water

EPA conducted three consecutive annual (2010, 2011, and 2012) ground water sampling events, and all laboratory total PCB results were below the MCL level of 0.5 µg/L. Ground water monitoring has been discontinued and the nine ground water monitoring wells were plugged and properly abandoned in 2012. Although a requirement for Five-Year Reviews was included in the decision documents, Five-Year Reviews were not conducted and are no longer required because the ground water data indicated that the concentration of total PCBs did not exceed the federal MCL of 0.5 µg/L and the Site met unlimited use/unrestricted exposure criteria for the soils and groundwater.

Quality Assurance and Quality Control (QA/QC)

The QA/QC program for the Third Removal Action was conducted in accordance with the Site Removal QA/QC Work Plan prepared by the EPA Superfund Technical Assessment and Response Team (START) contractor and the EPA Emergency and Rapid Response Services (ERRS) contractor. The START contractor was responsible for post-excavation confirmation, soil sample collection, and coordination of sample analyses performed by either the EPA Houston Laboratory or a commercial laboratory selected by the START contractor. All sample results were either validated by the EPA Houston Laboratory or by a START representative.

The cleanup activities met all QA/QC requirements for the Site. The EPA Remedial Project Manager (RPM) conducted daily oversight throughout the Removal Action activities. During the Removal Action the TCEQ Project Manager conducted routine inspections and was in regular contact with the RPM. The TCEQ Project Manager conducted two site visits to verify that construction was complete.

Community Involvement

Public participation activities have satisfied the requirements of CERCLA Section 113(k), 42 U.S.C. 9613(k) and CERCLA Section 117, 42 U.S.C. 9617. Throughout the Site's history, the community has been interested and involved with Site activities. EPA has kept the community and other interested parties updated on Site activities through informational meetings, fact sheets, and public meetings. Documents in the deletion docket which EPA relied on for recommendation for the deletion from the NPL are available to the public in the information repositories, and a notice of availability of the Notice of Intent for Deletion has been published in the Greenville Herald Banner.

Determination That the Site Meets the Criteria for Deletion in the NCP

The implemented remedy achieves the degree of cleanup specified in the ROD and ROD Amendment for all pathways of exposure. All selected remedial action objectives and clean-up goals are consistent with agency policy and guidance. No further Superfund responses are needed to protect human health and the environment at the Site.

In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate.

V. Deletion Action

The EPA, with concurrence of the State of Texas through the Texas Commission on Environment Quality, has determined that all appropriate response actions under CERCLA, have been completed. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication. This action will be effective September 10, 2018 unless EPA receives adverse comments by August 27, 2018. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion, and it will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: July 19, 2018.

Arturo Blanco,

Acting Regional Administrator, Region 6.

For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B to Part 300—[Amended]

■ 2. Table 1 of Appendix B to part 300 is amended in the table by removing the entry for “TX, Old Esco Manufacturing, Greenville”.

[FR Doc. 2018–16119 Filed 7–26–18; 8:45 am]

BILLING CODE 6560–50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2003–0010; FRL–9981–26—Region 5]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Peters Cartridge Factory Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 5 is publishing a direct final Notice of Partial Deletion of the Former Process Area (FPA) portion of the Peters Cartridge Factory Superfund Site in Kings Mills, Ohio from the National Priorities List (NPL). The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final Notice of Partial Deletion is being published by EPA with the concurrence of the State of Ohio, through the Ohio Environmental Protection Agency (OEPA), because EPA has determined that all appropriate response actions in the FPA under CERCLA, other than maintenance, monitoring and five-year reviews, have been completed. However, this partial deletion does not preclude future actions under Superfund.

DATES: This direct final partial deletion is effective September 25, 2018 unless EPA receives adverse comments by August 27, 2018. If adverse comments are received, EPA will publish a timely withdrawal of the direct final partial deletion in the **Federal Register** (FR) informing the public that the partial deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–2003–0010 at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Comments may also be submitted by email or mail to Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, Phone: (312) 886–6036, email address: cano.randolph@epa.gov or *hand deliver:* Superfund Records Center, U.S. Environmental Protection Agency,

Region 5, 77 West Jackson Boulevard, 7th Floor South, Chicago, IL 60604, Phone: (312) 886–0900. Such deliveries are only accepted during the Docket’s normal hours of operation, and special arrangements should be made for deliveries of boxed information. The normal business hours are Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SFUND–2003–0010. EPA’s policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or email. The <http://www.regulations.gov> website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or electronically or in hard copy at:

U.S. Environmental Protection Agency, Region 5, Superfund Records Center, 77 West Jackson Boulevard, 7th Floor South, Chicago, IL 60604, Phone:

(312) 886-0900, Hours: Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

Salem Township Library, 535 West Pike Street, Morrow, OH 45152, Phone: (513) 899-2588. Hours: Monday and Tuesday, 10:00 a.m. to 8:00 p.m. Wednesday and Thursday, 10:00 a.m. to 6:00 p.m. Friday, 10:00 a.m. to 5:00 p.m. Saturday, 10:00 a.m. to 2:00 p.m.

Warren County Administration Building, 406 Justice Drive, Lebanon, OH 45036, Phone: (513) 695-1000. Hours: Monday through Friday 8:00 a.m. to 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency, Region 5 (SR-6J), 77 West Jackson Boulevard, Chicago, IL 60604, Phone: (312) 886-6036, or via email at cano.randolph@epa.gov.

SUPPLEMENTARY INFORMATION:

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- I. Introduction
- II. NPL Deletion Criteria
- III. Partial Deletion Procedures
- IV. Basis for Site Partial Deletion
- V. Partial Deletion Action

I. Introduction

EPA Region 5 is publishing this direct final Notice of Partial Deletion for the Peters Cartridge Factory Site (Peters Cartridge Site), from the National Priorities List (NPL). This partial deletion pertains to the Former Process Area (FPA) portion of the Site, property identification numbers (PINs) 16-12-453-004, 16-12-453-005 and 16-12-400-012. The NPL constitutes Appendix B of the NCP, which EPA promulgated pursuant to CERCLA. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions (RA) financed by the Hazardous Substance Superfund (Fund). This partial deletion of the Peters Cartridge Site is proposed in accordance with 40 CFR 300.425(e) and is consistent with the Notice of Policy Change: Partial Deletion of Sites Listed on the National Priorities List. 60 FR 55466 (Nov. 1, 1995). As described in section 300.425(e)(3) of the NCP, a portion of a site deleted from the NPL remains eligible for Fund-financed RAs if future conditions warrant such actions.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the FPA of the Peters Cartridge Site and demonstrates how it meets the deletion criteria. Section V

discusses EPA's action to partially delete the FPA from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites, or portions thereof, may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the state, whether any of the following criteria have been met:

- i. Responsible parties or other persons have implemented all appropriate response actions required;
- ii. all appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or
- iii. the remedial investigation (RI) has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Pursuant to Section 121(c) of CERCLA, 42 U.S.C. 9621 and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of RAs where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews even if a site or a portion of a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Partial Deletion Procedures

The following procedures apply to the deletion of the FPA of the Peters Cartridge Site:

(1) EPA has consulted with the State of Ohio prior to developing this direct final Notice of Partial Deletion and the Notice of Intent for Partial Deletion co-published in the "Proposed Rules" section of the FR.

(2) EPA has provided the State 30 working days for review of this notice and the parallel Notice of Intent for Partial Deletion prior to their publication today, and the State, through the OEPA, has concurred on the partial deletion of the Site from the NPL.

(3) Concurrent with the publication of this direct final Notice of Partial Deletion, an announcement of the availability of the parallel Notice of Intent for Partial Deletion is being published in a major local newspaper, The Cincinnati Enquirer. The newspaper notice announces the 30-day public comment period concerning the Notice of Intent for Partial Deletion of the Site from the NPL.

(4) EPA placed copies of documents supporting the partial deletion in the deletion docket and made these items available for public inspection and copying at the Site information repositories identified above.

(5) If adverse comments are received within the 30-calendar day public comment period on this partial deletion action, EPA will publish a timely notice of withdrawal of this direct final Notice of Partial Deletion before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent for Partial Deletion and the comments already received.

Deletion of a portion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a portion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for further response actions, should future conditions warrant such actions.

IV. Basis for Site Partial Deletion

The following information provides EPA's rationale for deleting the FPA of the Peters Cartridge Site from the NPL:

Site Background and History

The Peters Cartridge Site (CERCLIS ID: OHD 987051083) is an approximately 71-acre parcel of land located along the south bank of the Little Miami River, in Warren County, Ohio. The Peters Cartridge Site is located at 1415 Grandin Road, Kings Mills, 45034, Hamilton Township, Ohio. Approximately one acre of the Site is located east of Grandin Road.

The Peters Cartridge Factory produced ordnance and shot shell ammunition at the Site from 1887 to 1934. The Remington Arms Company, Inc. (Remington) purchased the Peters Cartridge Factory in 1934 and continued the production of shot shell and cartridge ammunition at the facility. During the Second World War,

Remington produced .30 and .45-caliber carbine ammunition for the U.S. Government, until 1944, after which Remington discontinued operations at the facility.

The Peters Cartridge Site was subsequently divided into multiple land parcels that have been owned and occupied by various non-ammunition making entities since 1944. None of these companies are responsible for the contamination that is being addressed at the Site.

OEPA noted the release of possible hazardous substances at the Site in 1992. OEPA conducted a preliminary assessment in 1993 and brought the Site to the attention of EPA. OEPA conducted several screening investigations and evaluations at the Site between 1994 and 1999. During these investigations, OEPA collected soil, sediment, and groundwater samples. OEPA analyzed the samples for volatile organic compounds, semivolatile organic compounds (SVOCs), pesticides, and metals.

OEPA's investigations concluded that the Site was impacted by copper, lead, and mercury. These metals are associated with the former munitions manufacturing operations. The impacts appeared to be generally confined to surface soils in the former manufacturing and storage areas in the FPA. OEPA detected some SVOCs and pesticides in sediment samples from the Little Miami River, but these compounds were not found in soil or sediment samples from the Site and are not Site-related.

EPA proposed the Peters Cartridge Site to the NPL on April 30, 2003 (68 FR 23094). EPA finalized the Peters Cartridge Site on the NPL on September 18, 2012 after negotiations with potentially responsible parties (PRPs) to implement the cleanup remedy in EPA's 2009 Record of Decision (ROD) for the Site failed (77 FR 57495). The effective date of the final rule was October 18, 2012.

The Peters Cartridge Site is a single operable unit consisting of three areas: The FPA, which is the portion of the Site EPA is deleting from the NPL, and the Hamilton Township Property (HTP) and Lowland Area (LA) which are not being deleted and will remain on the NPL.

The FPA is the production portion of the Site where most of the Peters Cartridge manufacturing processes took place. The FPA is comprised of three parcels of developed land that total 14.29 acres and contain six buildings.

Most of the FPA is relatively flat and covered by buildings, concrete or asphalt paving, and small landscaped

areas. Discontinuous areas of ash-like fill were present around the buildings. Portions of the FPA are used by commercial or industrial businesses.

The HTP is a 56-acre parcel of unimproved wooded land south and southwest of the FPA. The HTP was primarily used to store the finished munitions manufactured at the Site. The HTP consists of steeply-sloping bedrock ridges and rolling topography with dense vegetation. The HTP contains bunkers, concrete supports, foundations, conveyance structures, and other facilities historically used by the Peters Cartridge Company.

The HTP contains a former salvage area in the northwestern portion of the property that is unpaved and is surrounded by a steel fence and mature woody and herbaceous vegetation. The former salvage area features buildings original to the former salvage yard and also contains discontinuous areas of ash-like fill. Hamilton Township plans to retain the HTP as open space.

The LA is located at the northern edge of the Site within the Little Miami River floodplain. The LA is differentiated from the rest of the Site by steel fencing, thick vegetation, and steep topography along the southern border of the Little Miami River Scenic Trail. The trail was a historical railroad right-of-way that was redeveloped as a bike and walking path.

North of the trail, the LA includes some historical manufacturing areas characterized by the presence of ash-like fill, concrete foundations, masonry structures, and concrete culverts/outfalls that drain surface water from the upland portions of the Site. Future land use in the LA is expected to remain recreational/open space.

This partial deletion pertains to all media within the FPA portion of the Peters Cartridge Site (see Current Site Layout in Docket Document ID EPA-HQ-SFUND-2003-0010-1954 in the Docket). The remaining areas of the Site, including the HTP and LA, will remain on the NPL and are not being considered for deletion as part of this action.

Remedial Investigation (RI) and Feasibility Study (FS)

The PRPs conducted a remedial investigation (RI) and feasibility study (FS) at the Site under a 2004 Administrative Order on Consent with EPA. The RI investigated the contamination at the Site and the FS evaluated potential cleanup alternatives to address the unacceptable Site risks identified in the human health and ecological risk assessments.

The PRPs conducted the RI in multiple phases from 2005 to 2009. The PRPs collected surface (zero to two feet below ground surface) and subsurface (greater than two feet below ground surface) soil samples from 112 soil boring locations in the FPA, 199 soil borings in the HTP, and 69 soil borings in the LA. The PRPs also collected samples of surface swale-soil from 29 locations in the HTP area, sediment samples from seven on-Site locations near the discharge points of the on-Site drainage features near the Little Miami River, 22 surface water sampling locations, and groundwater samples from eleven groundwater monitoring wells. The PRPs did not collect swale-soil samples from the FPA or LA because swale-soil was not present in these areas.

The results of the PRPs' human health risk assessment indicate that surface soil in the FPA posed an unacceptable risk to current commercial/industrial workers, utility workers and trespassers, and to future construction workers and residents. The risks were due to the concentrations of arsenic, benzo(a)pyrene, naphthalene and lead detected in the surface soil. The surface soil in the HTP posed an unacceptable risk to current trespassers and utility workers, and to future construction workers, residents and recreational users in the HTP. These risks were due to arsenic, benz(a)pyrene, lead and antimony detected in the HTP. The concentrations of lead in the LA surface soil posed an unacceptable risk to current utility workers, and to recreational users in off-trail areas.

The risk assessment determined that shallow, on-Site groundwater would pose an unacceptable cancer risk to potential future residents if the groundwater was used as a residential water supply. This risk is due to arsenic detected in the groundwater, but at concentrations below the Maximum Contaminant Level (MCL) for arsenic established under the Safe Drinking Water Act.

The current potential for human exposure to on-Site groundwater is limited, since the Site is used for commercial and industrial purposes and on-Site groundwater is not used for potable or any other uses, including irrigation. Potable water at the Site is currently supplied by the Warren County Water District. The groundwater is also at a depth where direct contact during intrusive activities is unlikely to occur.

The PRPs' ecological risk assessment indicated that surface soil in the terrestrial habits at the Site posed an unacceptable risk to ecological

receptors. The risks were due to the concentrations of antimony, arsenic, cadmium, copper, lead, mercury, nickel, selenium, thallium and zinc detected at the Site. The ecological risk assessment also identified potential ecological risks at the Site based on exposure to erosional material and surface water in the concrete-lined culverts at the Site, and to sediment and surface water in culvert outfalls along the shoreline of the Little Miami River.

OEPA conducted additional studies of the Little Miami River in 1999 and 2007. These studies indicated that Site-related contaminants were not impacting ecological receptors in the River. On-Site drainage features, however, had the potential to transport Site-related contaminants to surface water and river sediment.

The PRPs completed an FS in 2009. The FS developed and evaluated four cleanup alternatives to address the unacceptable risks at the Site. The FS evaluated soil remediation technologies to clean up the surface soil/swale contaminants in the FPA, HTP and LA, and in the upper six inches of shoreline sediment at culvert outfalls.

The FS determined that focusing the cleanup on the lead-impacted soil at the Site would result in the remediation of the other contaminants detected at the Site since the primary Site risk was due to exposure to lead-impacted soil. The FS also assumed that institutional controls (ICs) would be used to prevent residential land use and groundwater use at the Site.

Selected Remedy

EPA developed remedial action objectives (RAOs) to address the unacceptable risks to human health and the environment identified for exposure to on-Site soil/swale contaminants, the shoreline sediments in the Little Miami River, and groundwater.

EPA's RAOs for on-Site soil are to: Prevent human exposure to surface/swale soil having chemical concentrations resulting in a cumulative excess lifetime cancer risk greater than 1×10^{-4} or a non-cancer hazard index greater than 1; prevent human exposure to surface and subsurface soil with lead concentrations greater than EPA's residential standard (*i.e.*, 400 mg/kg) or, if an IC restricts residential development, prevent human exposure to surface/swale soil with lead concentrations greater than EPA's commercial standard (*i.e.*, 800 mg/kg); and prevent ecological receptor exposures to on-Site surface soil/swale soil with copper, lead, and mercury concentrations creating unacceptable levels of risk.

EPA's RAO for shoreline sediments is to prevent the exposure of aquatic receptors to contaminants of ecological concern in the Little Miami River by limiting the migration of Site-related contaminants in depositional material in the channelized outfalls and deltas bordering the river. This will be done by removing on-Site sources that contribute to elevated concentrations in the surface water discharged from the site.

EPA's RAO for groundwater is to prevent future residents from ingesting groundwater having an arsenic concentration that exceeds its MCL. This will be done as a limited RA using ICs to restrict groundwater use at the Site.

EPA selected a cleanup remedy for the Site in a Record of Decision (ROD) on September 28, 2009. The major components of the selected remedy detailed in the ROD are:

(1) Excavate surface soil in the FPA to a depth of at least two feet below ground surface (bgs) in areas that exceed the EPA commercial standard for lead of 800 milligrams per kilogram (mg/kg), and excavate surface soil in the HTP and LA to a depth of at least two feet bgs in areas that exceed the EPA residential standard for lead of 400 mg/kg. The actual areas to be excavated and depths will be determined and evaluated during the Remedial Design (RD). The excavated areas will be backfilled with clean fill material to the existing grade.

(2) Clean out and remove debris and erosional material at drainage culvert and outfall areas. Excavate three identified shoreline sediment areas to a depth of approximately six inches and backfill the shoreline sediment areas with clean fill material.

(3) Consolidate impacted soil, sediment, and erosional material in an on-Site consolidation cell. The cell will be constructed with an impermeable composite liner and cap system developed to be consistent with State regulations. A flexible membrane liner with a geotextile cushion will be installed as the main component of the cell liner system.

(4) Cap the consolidation cell with a composite cap system consisting of a six-inch-thick vegetative support layer, a two-foot-thick layer of compacted low-permeability clay, a geocomposite drainage layer, a flexible geomembrane, and a low-permeability clay layer beneath the geomembrane. The final cap design will be developed to be compliant with State regulations during the RD phase of the project. During the RD phase it will be determined whether an access restriction will be required based on future use of the area.

(5) Monitor groundwater to ensure that there is no migration of contaminants from the consolidation cell.

(6) ICs in the form of deed restrictions will be required to accomplish the following: Restrict land use to nonresidential purposes; limit future Site activities to prevent intrusive activities that could compromise the consolidation cell; and restrict on-Site groundwater from being used as a residential water supply.

(7) A review will be conducted within five years after the initiation of the RA and every five years thereafter to ensure that the selected remedy is still protective of human health and the environment, and will include a determination of whether land use changes have occurred or are likely to occur.

EPA issued a Unilateral Administrative Order to the lead PRP for the Site, E.I. du Pont de Nemours and Company (DuPont), to conduct the RD and RA work required by the ROD on March 30, 2012, after negotiations with DuPont and the other PRPs failed. DuPont conducted a Pre-Design Investigation (PDI) in 2012–2013. During the PDI, DuPont further delineated the extent of soil with lead concentrations above cleanup standards that would require excavation.

DuPont's PDI found that approximately 10,300 cubic yards of soil within the excavation areas outlined in the ROD was characteristically hazardous for lead based on the results of toxicity characteristic leaching procedure (TCLP) testing. The PDI also found that some of the characteristically hazardous lead-contaminated soil was located in some areas of the Site at depths greater than two feet bgs.

EPA issued an Explanation of Significant Differences (ESD) modifying the ROD based on the PDI in June 2015. The modified remedy required the excavation of all characteristically hazardous soils at the Site, regardless of depth. All soils with concentrations of lead considered to be characteristic hazardous waste were required to be stabilized to render them nonhazardous before being placed in the on-Site consolidation cell. Based on the PDI, the deepest excavation was estimated to be four feet bgs.

The ESD also made it clear that an Institutional Control Implementation and Assurance Plan (ICIAP) was required as part of the selected remedy. The ESD also explained EPA and OEPA's determination that a 2.0 percent final slope for the composite cap system over the on-Site consolidation cell was acceptable and provided a waiver of the

5.0 percent final slope requirements in Ohio Administrative Code 3745–29–08(C)(4)(c).

Response Actions

DuPont's contractor, Parsons, began RA construction activities at the Site in March 2015. Parsons excavated surface soil in the FPA with lead concentrations above EPA's commercial cleanup level for lead of 800 mg/kg from a depth of zero to two feet bgs; and surface/swale soil in the HTP and LA with concentrations above EPA's residential cleanup level for lead of 400 mg/kg from a depth of zero to two feet bgs.

Parsons additionally excavated all surface/swale and subsurface soil in the FPA, HTP and LA that exceeded EPA's hazardous waste TCLP concentration for lead of 5.0 milligrams/liter (mg/l), regardless of depth (zero to four feet).

Parsons consolidated the excavated soil in an on-Site consolidation cell Parsons constructed in the HTP at the southern end of the Site. Parsons treated the soil with TCLP concentrations above EPA's hazardous waste criteria with a proprietary in-situ stabilizing mixture that rendered the material nonhazardous prior to excavation and consolidation in the on-Site cell.

The excavated areas included: Most of the area sampled adjacent to and between the buildings in the FPA, and isolated areas on hill slopes behind the buildings; the HTP adjacent to the western portion of the FPA and LA; three small, isolated areas in the HTP upland areas; most of the portion of the LA between the Little Miami River Scenic Trail and the FPA; and isolated areas in the LA in the floodplain terrace along the Little Miami River and adjacent to Grandin Road. Four areas within the FPA and LA required excavation to four feet bgs to remove soil exceeding the regulatory level for TCLP lead.

Parsons backfilled the excavated areas with clean soil covered by six inches of clean topsoil to existing grade.

Parsons excavated the sediments from the on-Site drainage channels, concrete culverts and outfalls and consolidated these materials in the consolidation cell with the excavated soil. Parsons excavated and disposed of trash located in one area of the Site, including hazardous and nonhazardous soil and a small amount of asbestos-containing material, at appropriate off-Site disposal facilities.

The consolidation cell has a vegetated surface with a stone access road across the top of cap. The road provides access to the leachate sump and monitoring wells located on the north side of the cell.

Parsons submitted a Construction Completion Report documenting the completion of the RA construction activities to EPA and OEPA on June 7, 2017. EPA issued a letter approving DuPont's Construction Completion Report on June 26, 2017.

Cleanup Levels

The cleanup levels for the Site are: EPA's commercial cleanup level for lead of 800 mg/kg for surface soil in the FPA; EPA's residential cleanup level for lead of 400 mg/kg for surface soil in the HTP and LA; and EPA's TCLP hazardous waste leaching criteria of 5 mg/l for lead in all soil, regardless of depth. The ROD also requires groundwater use restrictions for on-Site groundwater with arsenic concentrations above the MCL of 10 micrograms/liter, and the excavation of debris and erosional material in on-Site culverts and outfalls, and of shoreline sediment in the Little Miami River.

Parsons determined the limits of the soil and sediment excavations, and the limits of soil stabilization required to meet the cleanup criteria in the ROD and ESD during the RD based on the results of the PDI. Parsons verified that all impacted soil was excavated to required limits by conducting surveys of the excavated areas before and after excavation for a point-by-point comparison. Parsons confirmed that all hazardous soil was properly treated prior to excavation by testing the stabilized soil in each grid for TCLP lead, arsenic, and mercury to confirm the soil was nonhazardous. All post-treatment samples passed the TCLP values for these compounds prior to excavation and consolidation in the on-Site cell except for one area which required a second round of treatment.

Parsons, EPA and OEPA verified that the sediment, debris and eroded materials were removed from the on-Site culverts, outfalls and the river shoreline through visual inspections conducted prior to and during an August 16, 2016 pre-final Site inspection.

Operation and Maintenance

DuPont is responsible for conducting operation and maintenance (O&M) at the Peters Cartridge Site consistent with a January 2017 O&M and ICIAP. The only O&M required for the FPA is to maintain, monitor and enforce the ROD-required IC, which is in the form of an Environmental Covenant (EC), and to conduct groundwater sampling, as needed.

The current owner of the FPA, Peters Cartridge Factory, LLC (PCF), filed the EC required by the ROD pursuant to

Ohio Revised Code §§ 5301.80 to 5301.92, on the FPA portion of the Peters Cartridge Site. PCF filed the EC with the Warren County Recorder's Office on January 30, 2018, Instrument 2018–003019. A copy of the recorded EC is in Docket Document ID EPA–HQ–SFUND–2003–0010–1942 in the Docket.

PCF's EC: (1) Restricts land use in the FPA to commercial and/or industrial use, and prohibits residential use of the property unless and until additional cleanup activities are performed and the EC is amended or terminated; (2) prohibits the extraction or use of groundwater beneath the FPA for any purpose, potable or otherwise, unless approved by EPA and for the purposes of investigation, monitoring, groundwater remediation or for a response activity; and (3) requires all excavation, digging, grading or disturbance of the ground surface in the FPA to be conducted in accordance with the September 2017 Soil Management Plan developed for the Site.

Five-Year Reviews

EPA is required to conduct statutory five-year reviews at the Peters Cartridge Site because hazardous substances, pollutants, or contaminants remain at the Site above levels that allow for unlimited use and unrestricted exposure. EPA must complete the first five-year review of the Site by December 12, 2019.

Community Involvement

EPA satisfied public participation activities for the Peters Cartridge Site required in Sections 113(k) and 117 of CERCLA, 42 U.S.C. 9613(k) and 9617. EPA developed a Community Involvement Plan for the Site in 2009. EPA made the RI/FS Report and Proposed Plan for the Site available to the public in June 2009. EPA placed copies of the RI/FS Report and Proposed Plan in the administrative record file maintained at the EPA Region 5 Records Center in Chicago, Illinois, and in the local information repositories for the Site at the Salem Township Library, 535 W Pike Street, Morrow, Ohio 45152 and the Warren County Administration Building, 406 Justice Drive, Lebanon, Ohio 45036. EPA also posted the RI/FS and Proposed Plan to the EPA Region 5 website at: <http://www.epa.gov/region5/sites/peterscartridge/index.htm>.

EPA published notices advertising the availability of the RI/FS Report and EPA's Proposed Plan for the Site in the Pulse-Journal, Little Miami/Kings Mills Edition and the Western Star, in Lebanon, Ohio on July 2, 2009.

EPA held a public comment period on its proposed cleanup plan for the Site

from July 6, 2009 through August 6, 2009. EPA also held a public meeting to present its Proposed Plan for the Site to a broader community audience on July 15, 2009. At the meeting, representatives from EPA and OEPA answered questions about the contamination at the Site and the cleanup alternatives that were considered.

EPA also used the meeting to solicit a wider cross-section of community input on the reasonably anticipated future land uses of the Site. Approximately 20 people attended the meeting, including representatives from the Little Miami River Group and Hamilton Township.

EPA considered the public comments received during the public meeting and public comment period prior to selecting a final remedy for the Site in the ROD. EPA's responses to the comments received are included in a Responsiveness Summary, which is part of the ROD.

EPA provided additional opportunities for public participation when issuing the ESD. Although there are no requirements to hold a public meeting or formal public comment period when an ESD is issued, EPA and OEPA voluntarily decided to conduct a public availability session to inform the local community of the changes in the original remedy and answer questions. EPA and OEPA chose to involve the local community because of the community's interest in the Site, and held an availability session on February 12, 2015. Approximately 40 people from the surrounding area attended the meeting.

EPA made the ESD available to the public by placing it in the administrative record with other documents supporting the ESD, in the information repositories. EPA also coordinated with OEPA to ensure that a notice summarizing the ESD and explaining EPA's reasons for the remedy changes was published in a local newspaper after the ESD was approved.

EPA published a notice announcing this direct final Notice of Partial Deletion in the Cincinnati Enquirer prior to publishing this deletion in the **Federal Register**. Documents in the deletion docket which EPA relied on to support the deletion of the FPA from the NPL are available to the public in the information repositories and at <http://www.regulations.gov>.

Determination That the Criteria for Partial Deletion Have Been Met

The FPA portion of the Peters Cartridge Site meets all of the site completion requirements specified in Office of Solid Waste and Emergency Response (OSWER) Directive 9320.22, Close-Out Procedures for National Priorities List Sites. All cleanup actions and RAOs for the FPA set forth in the 2009 ROD and 2015 ESD have been implemented for all pathways of exposure in the FPA. The selected RAs, RAOs, and associated cleanup levels for the FPA are consistent with EPA policy and guidance. No further Superfund response is necessary to protect human health or the environment in the FPA.

Section 300.425(e) of the NCP states that a Superfund site or a portion of a site may be deleted from the NPL when no further response action is appropriate. EPA, in consultation with the State of Ohio, has determined that all required response actions have been implemented at the FPA portion of the Peters Cartridge Site and that no further response action by the responsible parties is appropriate on this property.

V. Partial Deletion Action

EPA, with concurrence of the State of Ohio through the OEPA, has determined that all appropriate response actions under CERCLA, other than maintenance, monitoring and five-year reviews, have been completed at the FPA. Therefore, EPA is deleting the FPA portion of the Peters Cartridge Site, PINs 16-12-453-004, 16-12-453-005 and 16-12-400-012, from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is

taking it without prior publication. This action will be effective September 25, 2018 unless EPA receives adverse comments by August 27, 2018. If adverse comments are received within the 30-day public comment period, EPA will publish a timely notice of withdrawal of this direct final Notice of Partial Deletion before its effective date and the partial deletion will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to partially delete and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: July 17, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B to Part 300—[Amended]

■ 2. Table 1 of Appendix B to part 300 is amended by revising the listing under Ohio for “Peters Cartridge Factory” to read as follows:

Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes ^(a)
OH	Peters Cartridge Factory	Kings Mills	P

(a) * * *

* * *
P = Sites with partial deletion(s).

* * * * *

[FR Doc. 2018–16123 Filed 7–26–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 300**

[EPA–HQ–SFUND–2003–0010; FRL–9981–21—Region 8]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Davenport and Flagstaff Smelters Superfund Site**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 8 announces the deletion of the Davenport and Flagstaff Smelters Superfund Site (Site) located in Sandy City, Salt Lake County, Utah, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Utah, through the Utah Department of Environmental Quality (UDEQ), have determined that all appropriate response actions under CERCLA, other than operation and maintenance, and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: This action is effective July 27, 2018.**ADDRESSES:**

Docket: EPA has established a docket for this action under Docket Identification No. EPA–HQ–SFUND–2003–0010. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the site information repositories.

Locations, contacts, phone numbers and viewing hours are: Utah Department

of Environmental Quality, Salt Lake City, UT 84047; Phone: (801–944–7641); Hours: M–Th: 9 a.m.–9 p.m.; Fri–Sat: 9:00 a.m.–5:30 p.m.

FOR FURTHER INFORMATION CONTACT: Erna Waterman, Remedial Project Manager, U.S. Environmental Protection Agency, Region 8, EPA–SR, Denver, CO 80202, (303) 312–6762, email: waterman.erna@epa.gov.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is: Davenport and Flagstaff Smelters Superfund Site, Sandy City, Salt Lake County, Utah. A Notice of Intent to Delete for this Site was published in the **Federal Register** (83 FR 25635–25638) on June 4, 2018.

The closing date for comments on the Notice of Intent to Delete was July 5, 2018. No public comments were received.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial action. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system. Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future conditions warrant further actions.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: July 16, 2018.

Douglas H. Benevento,
Regional Administrator, Region 8.

For reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B to Part 300—[Amended]C

■ 2. Table 1 of appendix B to part 300 is amended in the table by removing the

entry for “UT, Davenport and Flagstaff Smelters, Sandy City, P”.

[FR Doc. 2018–16118 Filed 7–26–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 635**

[Docket No. 150121066–5717–02]

RIN 0648–XG327

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; closure of Angling category northern area trophy fishery.

SUMMARY: NMFS closes the northern area Angling category fishery for large medium and giant (“trophy” (*i.e.*, measuring 73 inches curved fork length or greater)) Atlantic bluefin tuna (BFT). This action is being taken to prevent further overharvest of the Angling category northern area trophy BFT subquota.

DATES: Effective 11:30 p.m., local time, July 26, 2018, through December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin or Tom Warren, (978) 281–9260.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Atlantic Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and amendments.

NMFS is required, under § 635.28(a)(1), to file a closure notice with the Office of the Federal Register for publication when a BFT quota is reached or is projected to be reached.

On and after the effective date and time of such notification, for the remainder of the fishing year or for a specified period as indicated in the notification, retaining, possessing, or landing BFT under that quota category is prohibited until the opening of the subsequent quota period or until such date as specified in the notice.

Angling Category Large Medium and Giant Northern “Trophy” Fishery Closure

The 2018 BFT fishing year, which is managed on a calendar-year basis and subject to an annual calendar-year quota, began January 1, 2018. The Angling category season opened January 1, 2018, and continues through December 31, 2018. The currently codified Angling category quota is 195.2 mt, of which 4.5 mt is allocated for the harvest of large medium and giant (trophy) BFT by vessels fishing under the Angling category quota, with 1.5 mt allocated for each of the following areas: North of 39°18' N lat. (off Great Egg Inlet, NJ) (the “northern area”); south of 39°18' N lat. and outside the Gulf of Mexico (the “southern area”); and in the Gulf of Mexico. Trophy BFT measure 73 inches (185 cm) curved fork length or greater.

Based on reported landings from the NMFS Automated Catch Reporting System, NMFS has determined that the codified Angling category northern area trophy BFT subquota has been reached and exceeded and that a closure of the northern area trophy BFT fishery is warranted. Therefore, retaining, possessing, or landing large medium or giant BFT north of 39°18' N lat. by persons aboard vessels permitted in the HMS Angling category and the HMS Charter/Headboat category (when fishing recreationally) must cease at 11:30 p.m. local time on July 26, 2018. This closure will remain effective through December 31, 2018. This action is intended to prevent further overharvest of the Angling category northern area trophy BFT subquota, and

is taken consistent with the regulations at § 635.28(a)(1). NMFS previously closed the 2018 trophy BFT fishery in the southern area on March 17, 2018 (83 FR 12141, March 20, 2018) and in the Gulf of Mexico on May 13, 2018 (83 FR 22602, May 16, 2018). Therefore, with this closure of the northern area trophy BFT fishery as of July 26, 2018, the Angling category trophy BFT fishery will be closed in all areas for 2018.

If needed, subsequent Angling category adjustments will be published in the **Federal Register**. Information regarding the Angling category fishery for Atlantic tunas, including daily retention limits for BFT measuring 27 inches (68.5 cm) to less than 73 inches and any further Angling category adjustments, is available at hmspermits.noaa.gov or by calling (978) 281-9260. HMS Angling and HMS Charter/Headboat category permit holders may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. Anglers are also reminded that all BFT that are released must be handled in a manner that will maximize survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the “Careful Catch and Release” brochure available at <https://www.fisheries.noaa.gov/resource/outreach-and-education/careful-catch-and-release-brochure>.

HMS Charter/Headboat and Angling category vessel owners are required to report the catch of all BFT retained or discarded dead, within 24 hours of the landing(s) or end of each trip, by accessing hmspermits.noaa.gov or by using the HMS Catch Reporting App.

Classification

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an

opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. The closure of the northern area Angling category trophy fishery is necessary to prevent any further overharvest of the northern area trophy fishery subquota. NMFS provides notification of closures by publishing the notice in the **Federal Register**, emailing individuals who have subscribed to the Atlantic HMS News electronic newsletter, and updating the information posted on the Atlantic Tunas Information Line at (978) 281-9260 and on hmspermits.noaa.gov.

These fisheries are currently underway and delaying this action would be contrary to the public interest as it could result in excessive trophy BFT landings that may result in future potential quota reductions for the Angling category, depending on the magnitude of a potential Angling category overharvest. NMFS must close the northern area trophy BFT fishery before additional landings of these sizes of BFT occur. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under 50 CFR 635.28(a)(1), and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: July 23, 2018.

Jennifer M. Wallace,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 2018-16038 Filed 7-24-18; 4:15 pm]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 83, No. 145

Friday, July 27, 2018

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0689; Product Identifier 2018-CE-016-AD]

RIN 2120-AA64

Airworthiness Directives; Gulfstream Aerospace Corporation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Gulfstream Aerospace Corporation (Gulfstream) Models G-IV and GIV-X airplanes. This proposed AD was prompted by reports of disbonding and surface cracking of the composite aft pressure bulkhead. This proposed AD would require inspections of the forward and aft surfaces of the pressure bulkhead composite panels for damage and repair of any damage found. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by September 10, 2018.

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

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

For service information identified in this NPRM, contact Gulfstream

Aerospace Corporation, P.O. Box 2206, Savannah, Georgia 31402-2206; telephone: (800) 810-4853; fax 912-965-3520; email: pubs@gulfstream.com; internet: http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm. You may view this service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0689; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800-647-5527) is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

William O. Herderich, Aerospace Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474-5547; fax: (404) 474-5605; email: william.o.herderich@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2018-0689; Product Identifier 2018-CE-016-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

We received reports of disbonding and accompanying surface cracking of the composite aft pressure bulkhead on Gulfstream Model G-IV airplanes. Gulfstream Model GIV-X airplanes have the same type design. During scheduled maintenance, areas with disbonding and accompanying surface cracks were found. Operational pressure loads by-passing the disbonded facesheet caused wrinkling or compression failure and led to the surface cracking. This condition, if not addressed, could result in structural failure of the bulkhead and loss of cabin pressure.

Airplanes maintained under Gulfstream's Maintenance Steering Group (MSG-3) maintenance program do not have a scheduled tap test inspection of the aft pressure bulkhead. Model G-IV airplanes with a serial number (S/N) 1400 through 1535, and Model GIV-X airplanes with a S/N 4001 through 4004 adopted the MSG-3 maintenance program in production. Airplanes produced earlier may change to the MSG-3 program by following the instructions in Aircraft Service Change (ASC) No. 416A, dated September 29, 2000.

Related Service Information Under 1 CFR Part 51

We reviewed Gulfstream G300 Customer Bulletin Number 243; Gulfstream G350 Customer Bulletin Number 198; Gulfstream G400 Customer Bulletin Number 243; Gulfstream G450 Customer Bulletin Number 198; and Gulfstream IV Customer Bulletin Number 243; all dated January 25, 2018. For the applicable airplanes, the service information describes procedures for inspecting the composite panels of the forward and aft pressure bulkhead for damage and repairing any damage found. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

We also reviewed ASC No. 416A, dated September 29, 2000, which contains instructions for changing the maintenance program for Model G-IV airplanes from the airplane's existing program to the MSG-3 maintenance program.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

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

Costs of Compliance

We estimate that this proposed AD affects 709 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	18 work-hours × \$85 per hour = \$1,530	Not applicable	\$1,530	\$1,084,770

The extent of damage found during the proposed inspection may vary from airplane to airplane. We have no way of determining the number of airplanes that might need repairs or the cost of such repairs for each airplane.

Authority for This Rulemaking

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

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

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to small airplanes, gliders, balloons, airships, domestic business jet transport airplanes, and associated appliances to the Director of the Policy and Innovation Division.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on

the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

(1) Is not a "significant regulatory action" under Executive Order 12866,
(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Gulfstream Aerospace Corporation: Docket No. FAA-2018-0689; Product Identifier 2018-CE-016-AD.

(a) Comments Due Date

We must receive comments by September 10, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the following Gulfstream Aerospace Corporation airplanes, certificated in any category:

(1) Model G-IV: Serial numbers (S/Ns) 1000 through 1399 that are maintained in accordance with the Maintenance Steering Group (MSG-3) maintenance program by complying with Aircraft Service Change (ASC) 416A; and S/Ns 1400 through 1535.

(2) Model GIV-X: S/Ns 4001 through 4004.

Note 1 to paragraph (c) of this AD: Model G-IV airplanes are also referred to by the marketing designations G300 and G400. Model GIV-X airplanes are also referred to by the marketing designations G350 and G450.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 53; fuselage.

(e) Unsafe Condition

This AD was prompted by reports of disbonding and surface cracking of the composite aft pressure bulkhead. We are issuing this AD to detect and address damage of the composite forward and aft pressure bulkhead. The unsafe condition, if not addressed, could result in structural failure of the bulkhead and loss of cabin pressure.

(f) Compliance

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

(g) Inspection

Within 12 months after the effective date of this AD, visually and tap inspect the forward and aft surfaces of the pressure bulkhead composite panels following the Accomplishment Instructions of the service information listed in paragraphs (g)(1) through (5) of this AD, as applicable to your model airplane.

(1) Gulfstream G300 Customer Bulletin Number 243, dated January 25, 2018;

(2) Gulfstream G350 Customer Bulletin Number 198, dated January 25, 2018;

(3) Gulfstream G400 Customer Bulletin Number 243, dated January 25, 2018;

(4) Gulfstream G450 Customer Bulletin Number 198, dated January 25, 2018;

(5) Gulfstream IV Customer Bulletin Number 243, dated January 25, 2018.

(h) Repairs

If any damage is found during the inspections required by this AD, before further flight, replace or repair the pressure bulkhead composite panels in accordance with FAA-approved procedures.

(i) Special Flight Permit

A special flight permit may be issued per 14 CFR 21.197 and 21.199 to operate the airplane to a facility to perform the inspection required by paragraph (g) of this AD. If damage is found during the inspection required by paragraph (g) of this AD, a special flight permit may be issued per 14 CFR 21.197 and 21.199 to operate the airplane to a location for repair, provided the aircraft is unpressurized.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(3) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (j)(3)(i) and (ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(k) Related Information

(1) For more information about this AD, contact William O. Herderich, Aerospace Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474-5547; fax: (404) 474-5605; email: william.o.herderich@faa.gov.

(2) For service information identified in this AD, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Savannah, Georgia 31402-2206; telephone: (800) 810-4853; fax 912-965-3520; email: pubs@gulfstream.com; internet: http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm. You may view this service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

Issued in Kansas City, Missouri, on July 20, 2018.

Pat Mullen,

Aircraft Certification Service, Acting Deputy Director, Policy & Innovation Division, AIR-601.

[FR Doc. 2018-15964 Filed 7-26-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2018-0370; Airspace Docket No. 18-AGL-11]

RIN 2120-AA66

Proposed Amendment of Class E Airspace; Wooster, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace extending upward from 700 feet above the surface at Wayne County Airport, Wooster, OH. The FAA is proposing this action as a result of an airspace review caused by the decommissioning of the Tiverton VHF omnidirectional range (VOR) navigation aid as part of the VOR Minimum Operational Network (MON) Program. The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before September 10, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366-9826, or (800) 647-5527. You must identify FAA Docket No. FAA-2018-0370; Airspace Docket No. 18-AGL-11, at the beginning of your comments. You may also submit comments through the internet at <http://www.regulations.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation

Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11B at NARA, call (202) 741-6030, or go to <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

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

FOR FURTHER INFORMATION CONTACT:

Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222-5711.

SUPPLEMENTARY INFORMATION:**Authority for This Rulemaking**

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped

postcard on which the following statement is made: "Comments to Docket No. FAA-2018-0370/Airspace Docket No. 18-AGL-11." The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRMs

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by amending the Class E airspace extending upward from 700 feet above the surface at Wayne County Airport, Wooster, OH, by removing the extension to the east associated with the Smith non-directional radio beacon. The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

Exclusionary language would be removed as it is no longer required. Also, the name of the city associated with the airport in the airspace description would be removed to comply with a change to FAA Order 7400.2L, Procedures for Handling Airspace Matters.

This action is necessary due to an airspace review caused by the decommissioning of the Tiverton VOR as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

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

* * * * *

AGL OH E5 Wooster, OH [Amended]

Wayne County Airport, OH
(Lat. 40°52'29" N, long. 81°53'18" W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Wayne County Airport.

Issued in Fort Worth, Texas, on July 16, 2018.

Walter Tweedy,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

[FR Doc. 2018-16012 Filed 7-26-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

[Docket ID ED-2018-OII-0062]

RIN 1855-AA14

Proposed Priorities, Requirements, Definitions, and Selection Criteria—Expanding Opportunity Through Quality Charter Schools Program; Grants to Charter Management Organizations for the Replication and Expansion of High-Quality Charter Schools

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Proposed priorities, requirements, definitions, and selection criteria.

SUMMARY: The Acting Assistant Deputy Secretary for Innovation and Improvement proposes priorities, requirements, definitions, and selection criteria for Grants to Charter Management Organizations for the Replication and Expansion of High-Quality Charter Schools (CMO grants) under the Expanding Opportunity

Through Quality Charter Schools Program (CSP), Catalog of Federal Domestic Assistance (CFDA) number 84.282M. The Acting Assistant Deputy Secretary for Innovation and Improvement may use one or more of these priorities, requirements, definitions, and selection criteria for competitions in fiscal year (FY) 2019 and later years. We take this action to support the replication and expansion of high-quality charter schools by charter management organizations (CMOs) throughout the Nation, particularly those that serve Educationally Disadvantaged Students,¹ such as students who are Individuals from Low-income Families, and students who traditionally have been underserved by charter schools, such as students who are Indians and students in Rural Communities.

DATES: We must receive your comments on or before August 27, 2018.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to www.regulations.gov to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under "Help."

- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments, address them to Allison Holte, U.S. Department of Education, 400 Maryland Avenue SW, Room 5W106, Washington, DC 20202-5970.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at www.regulations.gov. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT:

Allison Holte, U.S. Department of Education, 400 Maryland Avenue SW, Room 5W106, Washington, DC 20202-5970. Telephone: (202) 205-7726. Email: charterschools@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of This Regulatory Action:

The Acting Assistant Deputy Secretary for Innovation and Improvement proposes priorities, requirements, definitions, and selection criteria for CMO grants. The Acting Assistant Deputy Secretary for Innovation and Improvement may use one or more of these priorities, requirements, definitions, and selection criteria for future competitions, following publication of a notice of final priorities, requirements, definitions, and selection criteria in the **Federal Register**. We take this action in order to support the effective and efficient use of CSP funds in the replication and expansion of high-quality charter schools throughout the Nation, particularly those that serve Educationally Disadvantaged Students, such as students who are Individuals from Low-income Families, and students who traditionally have been underserved by charter schools, such as students who are Indians and students in Rural Communities.

Summary of the Major Provisions of This Regulatory Action: The Acting Assistant Deputy Secretary for Innovation and Improvement proposes this regulatory action to achieve two main goals.

First, we seek to continue to use funds under this program to support high-quality applications from highly qualified applicants. To that end, this document includes proposed priorities, requirements, definitions, and selection criteria that would encourage or require applicants to describe, for example: Past successes working with Academically Poor-performing Public Schools; experience operating or managing multiple charter schools; plans to expand their reach into new and diverse communities; logical connections between their proposed projects and intended outcomes for the students they propose to serve; and plans to evaluate the extent to which their proposed projects, if funded, yield intended outcomes.

Second, these proposed priorities, requirements, definitions, and selection criteria are designed to increase the likelihood that CMO grants support expanded high-quality educational opportunities for Educationally Disadvantaged Students, including students who are Individuals from Low-

income Families, children with disabilities, and English learners, as well as students who traditionally have been underserved by charter schools, such as students who are Indians and students in Rural Communities. Specifically, we propose priorities for applicants that would: Replicate or expand high-quality charter schools with an intentional focus on recruiting students from racially and socioeconomically diverse backgrounds, and maintaining racially and socially diverse student bodies; demonstrate that a meaningful proportion of the students served by the applicant are Individuals from Low-income Families; and replicate or expand high-quality charter schools that serve high school students, students in Rural Communities, or students who are Indians. Further, we propose requirements for CMO applicants to describe how the schools they intend to replicate or expand would recruit and enroll Educationally Disadvantaged Students and support such students in mastering State academic standards.

In addition to the proposed priorities, requirements, definitions, and selection criteria, we include in an Appendix the priorities, key requirements, definitions, and selection criteria from the Elementary and Secondary Education Act of 1965, as amended by the Every Student Succeeds Act (ESEA), and Federal regulations that are relevant to the CMO program and to the proposed priorities, requirements, definitions, and selection criteria. The priorities, requirements, definitions, and selection criteria in the Appendix are included for reference.

Costs and Benefits: The Department believes that the benefits of this regulatory action outweigh any associated costs, which we believe would be minimal. While this action would impose cost-bearing requirements on participating CMOs, we expect that CMO applicants would include requests for funds to cover such costs in their proposed project budgets. We believe this regulatory action would strengthen accountability for the use of Federal funds by helping to ensure that the Department awards CSP grants to CMOs that are most capable of expanding the number of high-quality charter schools available to our Nation's students. Please refer to the *Regulatory Impact Analysis* in this document for a more detailed discussion of costs and benefits.

Invitation to Comment: We invite you to submit comments regarding the proposed priorities, requirements, definitions, and selection criteria. To ensure that your comments have

¹ Throughout this document, terms for which we are proposing definitions are denoted by initial capitals.

maximum effect in developing the notice of final priorities, requirements, definitions, and selection criteria, we urge you to identify clearly the proposed priority, requirement, definition, or selection criterion that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866, 13563, and 13771 and their overall requirement of reducing regulatory burden that might result from these proposed priorities, requirements, definitions, and selection criteria. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of this program.

During and after the comment period, you may inspect all public comments about the proposed priorities, requirements, definitions, and selection criteria in 400 Maryland Avenue SW, Room 4W228, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the proposed priorities, requirements, definitions, and selection criteria. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The major purposes of the CSP are to: Expand opportunities for all students, particularly students facing educational disadvantages and students who traditionally have been underserved by charter schools, to attend high-quality charter schools and meet challenging State academic standards; provide financial assistance for the planning, program design, and initial implementation of public charter schools; increase the number of high-quality charter schools available to students across the United States; evaluate the impact of charter schools on student achievement, families, and communities; share best practices between charter schools and other public schools; encourage States to provide facilities support to charter schools; and support efforts to strengthen the charter school authorizing process. Through the CMO

grant program, the Department provides funds to CMOs on a competitive basis to enable them to replicate or expand one or more high-quality charter schools. More specifically, grant funds may be used to expand the enrollment of one or more existing high-quality charter schools, or to open one or more high-quality charter schools by replicating an existing high-quality charter school model.

Program Authority: Section 4305(b) of the ESEA.

Proposed Priorities:

This document contains seven proposed priorities.

Proposed Priority 1—Promoting Diversity.

Background: The CSP authorizing statute includes a priority under the CMO grant program for eligible entities that plan to operate or manage high-quality charter schools with racially and socioeconomically diverse student bodies. The proposed priority is based on the statutory priority, but would specify that the schools must have an intentional focus on racial and socioeconomic diversity. Accordingly, the proposed priority would help ensure that the Department targets for funding those CMOs taking active steps to promote racial and economic diversity in their schools, which we believe is consistent with the intent of the statutory priority.

A similar priority was included as a competitive preference priority in the FY 2017 notice inviting applications for this program (82 FR 4322) (FY 2017 NIA).

Proposed Priority: Under this priority, applicants must propose to replicate or expand high-quality charter schools that have an intentional focus on recruiting students from racially and socioeconomically diverse backgrounds and maintaining racially and socioeconomically diverse student bodies.

Proposed Priority 2—School Improvement through Restart Efforts.

Background: The CSP authorizing statute includes a priority under the CMO grant program for eligible entities that demonstrate success in working with schools identified by the State for comprehensive support and improvement under section 1111(c)(4)(D)(i) of the ESEA. States must identify schools for comprehensive support and improvement at the beginning of the 2018–19 school year. This proposed priority incorporates the statutory priority but, in order to meet the priority, the applicant also would be required to use CMO grant funds to support school improvement efforts by

restarting an Academically Poor-performing Public School. We believe that the restart model (*i.e.*, reopening a low-performing traditional public school under the management of a charter school developer or CMO, or reopening a low-performing public charter school under the management of a different charter school developer or CMO) holds promise as a school improvement strategy, but data suggest that it has been under-utilized thus far.² Accordingly, the proposed priority is intended to help increase the frequency of implementation of the restart model. The proposed priority also would allow applicants to demonstrate past success through work with persistently-lowest achieving schools or priority schools (*i.e.*, schools identified for interventions under the former School Improvement Grant program or in States that exercised “ESEA flexibility,” respectively, under the Elementary and Secondary Education Act of 1965, as amended by the No Child Left Behind Act of 2001).

In future CMO competitions that include this priority, we would encourage applicants to review CSP technical assistance materials pertaining to how an applicant may design an admissions lottery for an Academically Poor-performing Public School that the applicant is proposing to restart. Under the most recent version of the CSP nonregulatory guidance, for example, a charter school receiving CSP funds could, if permissible under applicable State law, exempt from its lottery students who are enrolled in the Academically Poor-performing Public School at the time it is restarted.

A similar priority was included as a competitive preference priority in the FY 2017 NIA.

Proposed Priority: Under this priority, the Secretary considers the extent to which applications—

(a) Demonstrate past success working with one or more Academically Poor-performing Public Schools or schools that previously were designated as persistently lowest-achieving schools or priority schools under the former School Improvement Grant program or in States that exercised ESEA flexibility, respectively, under the ESEA, as amended by NCLB; and

(b) Propose to use grant funds under this program to restart one or more Academically Poor-performing Public

² Hurlburt, S., Therriault, S.B., and Le Floch, K.C. (2012). School Improvement Grants: Analyses of State Applications and Eligible and Awarded Schools (NCEE 2012–4060). Washington, DC: National Center for Education Evaluation and Regional Assistance, Institute of Education Sciences, U.S. Department of Education.

Schools as charter schools during the project period by—

(i) Replicating one or more high-quality charter schools based on a successful charter school model for which the applicant has provided evidence of success; and

(ii) Targeting a demographically similar student population in the replicated charter schools as was served by the Academically Poor-performing Public Schools.

Proposed Priority 3—High School Students.

Background: Section 4305(b)(5)(C) of the ESEA authorizes the Secretary to give priority to applicants that propose to expand or replicate high-quality charter schools that serve high school students. In addition, section 4310(2)(M) of the ESEA authorizes charter schools that serve postsecondary students to receive CSP funds. The proposed priority incorporates the language of the statutory priority but, in order to meet the priority, applicants also would be required to replicate or expand charter high schools that offer programs and activities designed to prepare high school students for enrollment in a two- or four-year institution of higher education and, drawing from the authority provided in section 4310(2)(M), support such students after high school graduation in persisting in college and attaining degrees. The Department believes the proposed priority would complement broader efforts to promote a culture of lifelong learning and increase postsecondary participation, attendance, persistence, and degree attainment among our Nation's high school graduates.

Proposed Priority: Under this priority, applicants must propose to—

(i) Expand or replicate high-quality charter schools to serve high school students;

(ii) Prepare students in those schools for enrollment in a two- or four-year institution of higher education through programs and activities such as, but not limited to, accelerated learning programs (including Advanced Placement and International Baccalaureate courses and programs, dual or concurrent enrollment programs, and early college high schools), college counseling, career counseling, internships, work-based learning programs (such as apprenticeships), assisting students in the college admissions and financial aid application processes, and preparing students to take standardized college admissions tests;

(iii) Provide support for students who graduate from those schools and enroll

in a two- or four-year institution of higher education in persisting in, and attaining a degree from, such institutions, through programs and activities such as, but not limited to, mentorships, ongoing assistance with the financial aid application process, and establishing or strengthening peer support systems for such students attending the same institution; and

(iv) Propose one or more project-specific performance measures, including aligned leading indicators or other interim milestones, that will provide valid and reliable information about the applicant's progress in preparing students for enrolling in an institution of higher education and in supporting those students in persisting in and attaining a degree from such institutions. An applicant addressing this priority and receiving a grant under this program must provide data that are responsive to the measure(s), including performance targets, in its annual performance reports to the Department.

Proposed Priority 4—Low-Income Demographic.

Background: The proposed priority is for applicants with experience serving concentrations of students who are Individuals from Low-income Families and is intended to support efforts to increase the number of high-quality educational options available to such students, particularly in the Nation's high-poverty areas. We propose three subparts to this proposed priority, each of which would require that the schools the applicant operates or manages serve a specific minimum percentage of students who are Individuals from Low-income Families over the course of the CMO grant project period. The Secretary would have flexibility to choose one or more of the subparts of this priority in a given competition. We believe such flexibility is necessary to enable the Secretary to accommodate the range of eligible applicants and schools that may need support in a given year. The Department has included a similar priority in prior CMO competitions.

The Department expects that the charter schools proposed to be replicated or expanded by an applicant meeting this proposed priority would serve, for the duration of the grant period, a percentage of students who are Individuals from Low-income Families that is comparable to the minimum percentage of such students established under the priority for a given year.

Proposed Priority: Under this priority, applicants must demonstrate one of the following—

(i) That at least 40 percent of the students across all of the charter schools

the applicant operates or manages are Individuals from Low-income Families;

(ii) That at least 50 percent of the students across all of the charter schools the applicant operates or manages are Individuals from Low-income Families; or

(iii) That at least 60 percent of the students across all of the charter schools the applicant operates or manages are Individuals from Low-income Families.

Proposed Priority 5—Number of Charter Schools Operated or Managed by the Eligible Applicant.

Background: We propose this priority to enable the Department to distinguish applicants based on the number of charter schools they currently operate or manage. We propose three subparts for this priority, each of which would require that the applicant currently operate or manage a different number of schools. The Secretary would have the flexibility to choose one or more of the subparts of this priority in a given competition. This priority would give the Department flexibility to respond to changing funding needs in the charter school sector by, for example, targeting support toward smaller CMOs (*i.e.*, CMOs that currently operate or manage no more than five charter schools) as they begin to expand, or toward larger, more established CMOs that seek to serve new communities. In addition, given that the CSP statute, as reauthorized under the ESEA, now also allows State entities to award subgrants for the replication and expansion of high-quality charter schools, this priority would enable the Department to focus its grant-making, as appropriate, based on new and evolving support for the replication and expansion of charter schools at the State level.

Proposed Priority: Under this priority, applicants must demonstrate one of the following—

(i) That they currently operate or manage two to five charter schools;

(ii) That they currently operate or manage six to 20 charter schools; or

(iii) That they currently operate or manage 21 or more charter schools.

Proposed Priority 6—Geographic Location of Charter Schools Proposed to Be Replicated or Expanded.

Background: We propose this priority to enable the Department to provide incentives for applicants to propose to replicate or expand high-quality charter schools in Rural Communities. There is too often a relative dearth of high-quality educational options for students in Rural Communities, and our experience implementing this and other discretionary grant programs has taught us that these communities often face unique obstacles to educational success.

This proposed priority would allow the Department flexibility to provide an incentive for applicants proposing to replicate or expand high-quality charter schools in Rural Communities, including by evaluating such applications separately from applications proposing to replicate or expand high-quality charter schools in non-rural communities, thereby allowing for an “apples-to-apples” comparison. Accordingly, this proposed priority would help ensure that students in Rural Communities have access to a range of educational options similar to that available to their peers in suburban and urban areas, and from which parents can select an option that best meets their child’s needs.

Proposed Priority: Under this priority, applicants must propose to replicate or expand one or more high-quality charter schools in a:

- (i) Rural Community; or
- (ii) Community that is not a Rural Community.

Proposed Priority 7—Replicating or Expanding High-quality Charter Schools to Serve Students who are Indians.

Background: We propose this priority to enable the Department to provide an incentive for applicants that propose to replicate or expand high-quality charter schools by conducting targeted outreach and recruitment in order to serve a High Proportion of students who are Indians. We propose to define “High Proportion” in a way that would enable the Department to determine whether a replicated or expanded charter school serves a High Proportion of students who are Indians on a case-by-case basis, taking into consideration the unique factual circumstances of that school.

In order to meet the priority, an applicant would be required to provide a letter of support from one or more Indian Tribes or Indian Organizations located within the area to be served by the replicated or expanded charter school, and to demonstrate a commitment to meaningfully collaborate with the Indian Tribes or Indian Organizations in a timely, active, and ongoing manner. In addition, the applicant would have to demonstrate that the replicated or expanded charter school’s mission and educational program will address the unique educational needs of students who are Indians, and that such school’s governing board will have a substantial percentage of members who are members of Indian Tribes or Indian Organizations located within the area to be served by the charter school.

Priority: Under this priority, applicants must—

(i) Propose to replicate or expand one or more high-quality charter schools that—

(I) Utilize targeted outreach and recruitment in order to serve a High Proportion of students who are Indians;

(II) Have a mission and academic program that will address the unique educational needs of students who are Indians, including through the use of instructional programs and teaching methods that reflect and preserve Indian language, culture, and history; and

(III) Have a governing board with a substantial percentage of members who are members of Indian Tribes or Indian Organizations located within the area to be served by the replicated or expanded charter school;

(ii) Submit a letter of support, from at least one Indian Tribe or Indian Organization located within the area to be served by the replicated or expanded charter school; and

(iii) Demonstrate a commitment to meaningfully collaborate with the Indian Tribe(s) or Indian Organization(s) from which the applicant has received a letter of support in a timely, active, and ongoing manner with respect to the development and implementation of the educational program at the charter school.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Proposed Requirements:

Background: The ESEA includes several requirements for applications submitted under this program. We have listed the statutory application requirements in the Appendix for

reference. In addition to the specific statutory requirements, section 4305(c) of the ESEA requires grants awarded to CMOs to have the “same terms and conditions as grants awarded to State entities under section 4303.” We propose some requirements for this program that apply to State entity grants under section 4303(f). We have included in the Appendix to this document other requirements in section 4303(f) that we intend to apply to CMO grants but that do not require rulemaking. In applying the latter requirements to CMO grants, references to “State entity” and “State entity program” must be read as references to “charter management organization” and “grant award,” respectively.

In general, the Department believes, based on past experience administering this program, that these proposed requirements are necessary for the proper consideration of applications for CMO grants and would increase the likelihood of success of applicants’ proposed projects, thereby contributing to the efficient use of taxpayer dollars in expanding the high-quality educational options available to our Nation’s students. In accordance with section 4305(c), these proposed requirements would not preclude the Department from applying other terms and conditions applicable to State entity grants to CMO grants in FY 2019 or future years.

Proposed Requirements: The Acting Assistant Deputy Secretary for Innovation and Improvement proposes the following requirements for this program. We would apply one or more of these requirements in any year in which this program is in effect.

Applicants for funds under this program must meet one or more of the following requirements—

(a) Demonstrate that the applicant currently operates or manages more than one charter school. For purposes of this program, multiple charter schools are considered to be separate schools if each school—

(i) Meets each element of the definition of “charter school” under section 4310(2) of the ESEA; and

(ii) Is treated as a separate school by its authorized public chartering agency and the State in which the charter school is located, including for purposes of accountability and reporting under title I, part A of the ESEA.

(b) Provide information regarding any compliance issues and how they were resolved, for any charter schools operated or managed by the applicant that have—

(i) Closed;

(ii) Had their charter(s) revoked due to problems with statutory or regulatory compliance, including compliance with sections 4310(2)(G) and (J) of the ESEA; or

(iii) Had their affiliation with the applicant revoked or terminated, including through voluntary disaffiliation.

(c) Provide a complete logic model (as defined in 34 CFR 77.1) for the grant project. The logic model must include the applicant's objectives for replicating or expanding one or more high-quality charter schools with funding under this program, including the number of high-quality charter schools the applicant proposes to replicate or expand.

(d) If the applicant currently operates, or is proposing to replicate or expand, a single-sex charter school or coeducational charter school that provides a single-sex class or extracurricular activity (collectively referred to as a "single-sex educational program"), demonstrate that the existing or proposed single-sex educational program is in compliance with Title IX of the Education Amendments of 1972 (20 U.S.C. 1681, *et seq.*) (Title IX) and its implementing regulations, including 34 CFR 106.34.

(e) Describe how the applicant currently operates or manages the high-quality charter schools for which it has presented evidence of success and how the proposed replicated or expanded charter schools will be operated or managed, including the legal relationship between the applicant and its schools. If a legal entity other than the applicant has entered or will enter into a performance contract with an authorized public chartering agency to operate one or more of the applicant's schools, the applicant must also describe its relationship with that entity.

(f) Describe how the applicant will solicit and consider input from parents and other members of the community on the implementation and operation of each replicated or expanded charter school, including in the area of school governance.

(g) Describe the lottery and enrollment procedures that will be used for each replicated or expanded charter school if more students apply for admission than can be accommodated, including how any proposed weighted lottery complies with section 4303(c)(3)(A) of the ESEA.

(h) Describe how the applicant will ensure that all eligible students with disabilities receive a free appropriate public education in accordance with part B of the Individuals with Disabilities Education Act.

(i) Describe how the proposed project will assist Educationally Disadvantaged Students in mastering challenging State academic standards.

(j) Provide a budget narrative, aligned with the activities, target grant project outputs, and outcomes described in the logic model, that outlines how Federal grant funds will be expended to carry out planned activities.

(k) Provide the applicant's most recent independently audited financial statements prepared in accordance with generally accepted accounting principles.

(l) Describe the applicant's policies and procedures to assist students enrolled in a charter school that closes or loses its charter to attend other high-quality schools.

(m) Provide—

(A) A request and justification for waivers of any Federal statutory or regulatory provisions that the eligible entity believes are necessary for the successful operation of the charter schools to be replicated or expanded; and

(B) A description of any State or local rules, generally applicable to public schools, that will be waived, or otherwise not apply to such schools.

Proposed Definitions:

The Acting Assistant Deputy Secretary for Innovation and Improvement proposes the following definitions for this program. We may apply one or more of these definitions in any year in which this program is in effect.

Background: In order to ensure common understanding of the proposed priorities, requirements, and selection criteria, we propose nine definitions of terms that are critical to the policy and statutory purposes of the CMO grant program. We propose these definitions in order to clarify expectations for eligible entities applying for CMO grants and to ensure that the review process for applications for CMO grants remains as transparent as possible. The proposed definition for Educationally Disadvantaged Students is based on section 1115(c)(2) of the ESEA, the proposed definition for Indian is taken from section 6151(3) of the ESEA, the proposed definition for Indian Organization is from 34 CFR 263.3, and the proposed definition for Indian Tribe is from section 6132(b)(2) of the ESEA.

Academically poor-performing public school means:

(a) A school identified by the State for comprehensive support and improvement under section 1111(c)(4)(D)(i) of the ESEA; or

(b) A public school otherwise identified by the State, or in the case of

a charter school, its authorized public chartering agency, as similarly academically poor-performing.

Educationally disadvantaged student means a student in one or more of the categories described in section 1115(c)(2) of the ESEA, which include children who are economically disadvantaged, students with disabilities, migrant students, English learners, neglected or delinquent students, homeless students, and students who are in foster care.

High proportion, when used to refer to students who are Indians, is a fact-specific, case-by-case determination based upon the unique circumstances of a particular charter school or proposed charter school. The Secretary considers "high proportion" to include a majority of students who are Indians. In addition, the Secretary may determine that less than a majority of students who are Indians constitutes a "high proportion" based on the unique circumstances of a particular charter school or proposed charter school, as described in the application for funds.

Indian means an individual who is—

(A) A member of an Indian tribe or band, as membership is defined by the tribe or band, including—

(i) Any tribe or band terminated since 1940; and

(ii) Any tribe or band recognized by the State in which the tribe or band resides;

(B) A descendant, in the first or second degree, of an individual described in subparagraph (A);

(C) Considered by the Secretary of the Interior to be an Indian for any purpose;

(D) An Eskimo, Aleut, or other Alaska Native; or

(E) A member of an organized Indian group that received a grant under the Indian Education Act of 1988 as in effect the day preceding the date of enactment of the Improving America's Schools Act of 1994.

Indian organization means an organization that—

(1) Is legally established—

(i) By tribal or inter-tribal charter or in accordance with State or tribal law; and

(ii) With appropriate constitution, by-laws, or articles of incorporation;

(2) Includes in its purposes the promotion of the education of Indians;

(3) Is controlled by a governing board, the majority of which is Indian;

(4) If located on an Indian reservation, operates with the sanction or by charter of the governing body of that reservation;

(5) Is neither an organization or subdivision of, nor under the direct control of, any institution of higher education; and

(6) Is not an agency of State or local government.

Indian tribe means a federally-recognized or a State-recognized tribe.

Individual from a low-income family means an individual who is determined by a State educational agency or local educational agency to be a child from a low-income family on the basis of (a) data used by the Secretary to determine allocations under section 1124 of the ESEA, (b) data on children eligible for free or reduced-price lunches under the Richard B. Russell National School Lunch Act, (c) data on children in families receiving assistance under part A of title IV of the Social Security Act, (d) data on children eligible to receive medical assistance under the Medicaid program under Title XIX of the Social Security Act, or (e) an alternate method that combines or extrapolates from the data in items (a) through (d) of this definition.

Rural community means a community that is served by a local educational agency that is eligible to apply for funds under the Small Rural School Achievement (SRSA) program or the Rural and Low-Income School (RLIS) program authorized under title V, part B of the ESEA. Applicants may determine whether a particular local educational agency is eligible for these programs by referring to information on the following Department websites. For the SRSA program: www2.ed.gov/programs/reaprsra/eligible16/index.html. For the RLIS program: www2.ed.gov/programs/reaprlisp/eligibility.html.

Proposed Selection Criteria:

Background: The ESEA includes three selection criteria for the CMO grant program, which are included in the Appendix for reference. We propose a criterion that would expand upon those included in the authorizing statute, as well as three other criteria. Based on past experience implementing the CMO grant program, we believe that these additional criteria will be valuable tools for peer reviewers to evaluate the quality of CMO applications in future years.

Specifically, proposed selection criterion (a) "Quality of the Eligible Applicant" derives from the ESEA selection criteria for this program, under which the Department considers the degree to which an applicant has demonstrated success in increasing student academic achievement and whether charter schools operated or managed by the applicant have been closed or have encountered statutory or regulatory compliance issues. The proposed criterion would expand on the statutory criteria by examining the extent to which academic achievement

results for Educationally Disadvantaged Students attending an applicant's schools have exceeded State averages for such students in the State. Further, we propose to incorporate into this criterion language from the ESEA definition of "high-quality charter school" that would enable reviewers also to consider any significant issues that an applicant's charter schools have encountered in the areas of financial or operational management and student safety. The Department believes that these proposed selection factors would align with the intent of the authorizing statute and would bolster our ability to select high-quality CMO applicants.

Proposed selection criterion (b) "Contribution in assisting Educationally Disadvantaged Students" would focus on the contribution the proposed project would make in expanding educational opportunities for Educationally Disadvantaged Students and enabling those students to meet challenging State academic standards. This proposed criterion would allow the Department to assess the extent to which each proposed project aligns with a major statutory purpose of the CSP: To expand opportunities for Educationally Disadvantaged Students. This criterion would encourage applicants to discuss (1) their current capacity to serve Educationally Disadvantaged Students, including students with disabilities and English learners, and to compare that capacity to that of surrounding public schools, and (2) their plans for replicating or expanding high-quality charter schools that will recruit and enroll Educationally Disadvantaged Students.

Proposed selection criterion (c) "Quality of the evaluation plan for the proposed project" would examine how applicants would evaluate their proposed projects. It is crucial that the Department invest its limited discretionary funding in projects that are based on a reasoned theory and that are likely to yield information that can be used to continue to expand high-quality educational options for students. This criterion would allow the Department to assess the extent to which each CMO applicant: Has based its proposed project on a logic model (as defined in 34 CFR 77.1) that links the planned inputs and outputs to clearly defined intended outcomes of the project; will use objective performance measures to ensure that the project remains on track to meet stated objectives; and will be able to produce qualitative and quantitative data by the end of the grant period.

Finally, proposed selection criterion (d) "Quality of the management plan

and personnel" would allow applicants to highlight the management plan for their proposed project, the qualifications of key project personnel, and the potential for sustaining the charter schools included in the proposed project after the grant has expired. While similar selection factors exist in the general selection criteria in 34 CFR 75.210, our intent for this proposed selection criterion is to focus on the extent to which the applicant could demonstrate its specific experience with, and proposed management plan for, replicating or expanding high-quality charter schools. We believe, based on past experience implementing this program, that the proposed criterion is appropriate to ascertain the likelihood of an applicant's success.

Proposed Selection Criteria: The Acting Assistant Deputy Secretary for Innovation and Improvement proposes the following selection criteria for evaluating an application under this program. We may apply one or more of these criteria in any year in which this program is in effect. In the NIA, we will announce the maximum possible points assigned to each criterion.

The Secretary will select eligible entities to receive grants under this program on the basis of the quality of such applications, after taking into consideration one or more of the following selection criteria:

(a) *Quality of the eligible applicant.* In determining the quality of the eligible applicant, the Secretary considers one or more of the following factors:

(i) The extent to which the academic achievement results (including annual student performance on statewide assessments and annual student attendance and retention rates, and where applicable and available, student academic growth, high school graduation rates, college attendance rates, and college persistence rates) for Educationally Disadvantaged Students served by the charter schools operated or managed by the applicant have exceeded the average academic achievement results for such students in the State.

(ii) The extent to which one or more charter schools operated or managed by the applicant have closed; have had a charter revoked due to noncompliance with statutory or regulatory requirements; or have had their affiliation with the applicant revoked or terminated, including through voluntary disaffiliation.

(iii) The extent to which one or more charter schools operated or managed by the applicant have had any significant issues in the area of financial or

operational management or student safety or have otherwise experienced significant problems with statutory or regulatory compliance that could lead to revocation of the school's charter.

(b) *Contribution in assisting Educationally Disadvantaged Students.*

The significance of the contribution the proposed project will make in expanding educational opportunities for Educationally Disadvantaged Students and enabling those students to meet challenging State academic standards. In determining the significance of the contribution the proposed project will make, the Secretary considers one or more of the following factors:

(i) The extent to which charter schools currently operated or managed by the applicant serve Educationally Disadvantaged Students, including students with disabilities and English learners, at rates comparable to surrounding public schools or, in the case of virtual charter schools, at rates comparable to public schools in the State.

(ii) The quality of the plan to ensure that the charter schools the applicant proposes to replicate or expand will recruit and enroll Educationally Disadvantaged Students.

(c) *Quality of the evaluation plan for the proposed project.*

In determining the quality of the evaluation plan for the proposed project, the Secretary considers the extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the proposed project, as articulated in the applicant's logic model (as defined in 34 CFR 77.1), and that will produce quantitative and qualitative data by the end of the grant period.

(d) *Quality of the management plan.*

In determining the quality of the applicant's management plan, the Secretary considers the ability of the applicant to sustain the operation of the replicated or expanded charter schools after the grant has ended, as demonstrated by the multi-year financial and operating model required under section 4305(b)(3)(B)(iii) of the ESEA.

Final Priorities, Requirements, Definitions, and Selection Criteria:

We will announce the final priorities, requirements, definitions, and selection criteria in a document in the **Federal Register**. We will determine the final priorities, requirements, definitions, and selection criteria after considering public comments and other information available to the Department. This document does not preclude us from proposing additional priorities,

requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use one or more of these priorities, requirements, definitions, and selection criteria, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866, 13563, and 13771

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an "economically significant" rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those

approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include "identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes."

We are issuing these proposed priorities, requirements, definitions, and selection criteria only on a reasoned determination that their benefits would justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

Discussion of Potential Costs and Benefits

The Department believes that this regulatory action would not impose significant costs on eligible entities, whose participation in this program is voluntary. While this action would impose some requirements on participating CMOs that are cost-bearing, the Department expects that applicants for this program would include in their proposed budgets a request for funds to support compliance

with such cost-bearing requirements. Therefore, costs associated with meeting these requirements are, in the Department's estimation, minimal.

This regulatory action would strengthen accountability for the use of Federal funds by helping to ensure that the Department selects for CSP grants the CMOs that are most capable of expanding the number of high-quality charter schools available to our Nation's students, consistent with a major purpose of the CSP as described in section 4301(3) of the ESEA. The Department believes that these benefits to the Federal government and to SEAs outweigh the costs associated with this action.

Regulatory Alternatives Considered

The Department believes that the proposed priorities, requirements,

definitions, and selection criteria are needed to administer the program effectively. As an alternative to promulgating the proposed selection criteria, the Department could choose from among the selection criteria authorized for CSP grants to CMOs in section 4305(b) of the ESEA (20 U.S.C. 7221c) and the general selection criteria in 34 CFR 75.210. We do not believe that these criteria provide a sufficient basis on which to evaluate the quality of applications. In particular, the criteria would not sufficiently enable the Department to assess an applicant's past performance with respect to the operation of high-quality charter schools or with respect to compliance issues that the applicant has encountered.

We note that several of the proposed priorities, requirements, definitions, and

selection criteria are based on priorities, requirements, definitions, selection criteria, and other provisions in the authorizing statute for this program.

Accounting Statement

As required by OMB Circular A-4 (available at www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf), in the following table we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this regulatory action. This table provides our best estimate of the changes in annual monetized transfers as a result of this regulatory action. Expenditures are classified as transfers from the Federal Government to SEAs.

ACCOUNTING STATEMENT CLASSIFICATION OF ESTIMATED EXPENDITURES [In millions]

Category	Transfers
Annualized Monetized Transfers	\$90.
From Whom To Whom?	From the Federal Government to CMOs.

Under Executive Order 13771, for each new regulation that the Department proposes for notice and comment or otherwise promulgates that is a significant regulatory action under Executive Order 12866 and that imposes total costs greater than zero, it must identify two deregulatory actions. For Fiscal Year 2018, any new incremental costs associated with a new regulation must be fully offset by the elimination of existing costs through deregulatory actions. However, Executive Order 13771 does not apply to "transfer rules" that cause only income transfers between taxpayers and program beneficiaries, such as those regarding discretionary grant programs. These proposed priorities, requirements, definitions, and selection criteria would be utilized in connection with a discretionary grant program and, therefore, Executive Order 13771 is not applicable.

Paperwork Reduction Act of 1995

The proposed priorities, requirements, and selection criteria contain information collection requirements that are approved by OMB under OMB control number 1894-0006; the proposed priorities, requirements, and selection criteria do not affect the currently approved data collection.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR

part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotope, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov.

Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: July 23, 2018.

James C. Blew,

Acting Assistant Deputy Secretary for Innovation and Improvement.

Appendix

This Appendix includes priorities, requirements, definitions, and selection criteria from sections 4303(f), 4305(b), 4305(c), and 8101 of the ESEA and 34 CFR 77.1 for reference.

Priorities: The following priorities are from section 4305(b)(5) of the ESEA:

(5) Priority.—In awarding grants under this section, the Secretary shall give priority to eligible entities that—

(A) Plan to operate or manage high-quality charter schools with racially and socioeconomically diverse student bodies;

(B) Demonstrate success in working with schools identified by the State for comprehensive support and improvement under section 1111(c)(4)(D)(i);

(C) Propose to use funds—
(i) To expand high-quality charter schools to serve high school students; or

(ii) To replicate high-quality charter schools to serve high school students; or
(D) Propose to operate or manage high-quality charter schools that focus on dropout recovery and academic re-entry.

Requirements and Assurances: The following requirements and assurances are from sections 4303(f) and 4305(b)(3), respectively, of the ESEA. In accordance with section 4305(c), we include in this Appendix

key statutory provisions in section 4303(f) that apply to State entity grants that we intend to apply to CMO grants. In applying the requirements in section 4303(f) to CMO grants, references to “State entity” and “State entity program” must be read as references to “charter management organization” and “grant award,” respectively.

4303(f) Applications.—A State entity desiring to receive a grant under this section shall submit an application to the Secretary at such time and in such manner as the Secretary may require. The application shall include the following:

(1) **Description of program.**—A description of the State entity’s objectives in running a quality charter school program under this section and how the program will be carried out, including—

(A) A description of how the State entity will—

(x) Ensure that charter schools receiving funds under the State entity’s program meet the educational needs of their students, including children with disabilities and English learners; and

(xiii)(E) A description of how the State entity will ensure that each charter school receiving funds under the State entity’s program has considered and planned for the transportation needs of the school’s students.

(2) **Assurances.**—Assurances that—

(B) The State entity will support charter schools in meeting the educational needs of their students, as described in paragraph (1)(A)(x); and

(G) The State entity will ensure that each charter school receiving funds under the State entity’s program makes publicly available, consistent with the dissemination requirements of the annual State report card under section 1111(h), including on the website of the school, information to help parents make informed decisions about the education options available to their children, including—

(i) Information on the educational program;

(ii) Student support services;

(iii) Parent contract requirements (as applicable), including any financial obligations or fees;

(iv) Enrollment criteria (as applicable); and

(v) Annual performance and enrollment data for each of the subgroups of students, as defined in section 1111(c)(2), except that such disaggregation of performance and enrollment data shall not be required in a case in which the number of students in a group is insufficient to yield statically reliable information or the results would reveal personally identifiable information about an individual student.

4305(b)(3) Application Requirements.—An eligible entity desiring to receive a grant under this subsection shall submit an application to the Secretary at such time and in such manner as the Secretary may require. The application shall include the following:

(A) **Existing Charter School Data.**—For each charter school currently operated or managed by the eligible entity—

(i) Student assessment results for all students and for each subgroup of students described in section 1111(c)(2);

(ii) Attendance and student retention rates for the most recently completed school year

and, if applicable, the most recent available four-year adjusted cohort graduation rates and extended-year adjusted cohort graduation rates; and

(iii) Information on any significant compliance and management issues encountered within the last three school years by any school operated or managed by the eligible entity, including in the areas of student safety and finance.

(B) **Descriptions.**—A description of—

(i) The eligible entity’s objectives for implementing a high-quality charter school program with funding under this subsection, including a description of the proposed number of high-quality charter schools the eligible entity proposes to open as a result of the replication of a high-quality charter school or to expand with funding under this subsection;

(ii) The educational program that the eligible entity will implement in such charter schools, including—

(I) Information on how the program will enable all students to meet the challenging State academic standards;

(II) The grade levels or ages of students who will be served; and

(III) The instructional practices that will be used;

(iii) How the operation of such charter schools will be sustained after the grant under this subsection has ended, which shall include a multi-year financial and operating model for the eligible entity;

(iv) How the eligible entity will ensure that such charter schools will recruit and enroll students, including children with disabilities, English learners, and other educationally disadvantaged students; and

(v) Any request and justification for any waivers of Federal statutory or regulatory requirements that the eligible entity believes are necessary for the successful operation of such charter schools.

(C) **Assurance.**—An assurance that the eligible entity has sufficient procedures in effect to ensure timely closure of low-performing or financially mismanaged charter schools and clear plans and procedures in effect for the students in such schools to attend other high-quality schools.

Definitions: The following definitions are from the ESEA or Department regulations. The specific source of each definition is noted in parentheses following each definition.

Authorized public chartering agency means a State educational agency, local educational agency, or other public entity that has the authority pursuant to State law and approved by the Secretary to authorize or approve a charter school. (Section 4310(1) of the ESEA)

Charter school means a public school that—

(A) In accordance with a specific State statute authorizing the granting of charters to schools, is exempt from significant State or local rules that inhibit the flexible operation and management of public schools, but not from any rules relating to the other requirements of this paragraph;

(B) Is created by a developer as a public school, or is adapted by a developer from an existing public school, and is operated under public supervision and direction;

(C) Operates in pursuit of a specific set of educational objectives determined by the school’s developer and agreed to by the authorized public chartering agency;

(D) Provides a program of elementary or secondary education, or both;

(E) Is nonsectarian in its programs, admissions policies, employment practices, and all other operations, and is not affiliated with a sectarian school or religious institution;

(F) Does not charge tuition;

(G) Complies with the Age Discrimination Act of 1975, title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), section 444 of the General Education Provisions Act (20 U.S.C. 1232g) (commonly referred to as the “Family Educational Rights and Privacy Act of 1974”), and part B of the Individuals with Disabilities Education Act;

(H) Is a school to which parents choose to send their children, and that—

(i) Admits students on the basis of a lottery, consistent with section 4303(c)(3)(A), if more students apply for admission than can be accommodated; or

(ii) In the case of a school that has an affiliated charter school (such as a school that is part of the same network of schools), automatically enrolls students who are enrolled in the immediate prior grade level of the affiliated charter school and, for any additional student openings or student openings created through regular attrition in student enrollment in the affiliated charter school and the enrolling school, admits students on the basis of a lottery as described in clause (i);

(I) Agrees to comply with the same Federal and State audit requirements as do other elementary schools and secondary schools in the State, unless such State audit requirements are waived by the State;

(J) Meets all applicable Federal, State, and local health and safety requirements;

(K) Operates in accordance with State law;

(L) Has a written performance contract with the authorized public chartering agency in the State that includes a description of how student performance will be measured in charter schools pursuant to State assessments that are required of other schools and pursuant to any other assessments mutually agreeable to the authorizing public chartering agency and the charter school; and

(M) May serve students in early childhood education programs or postsecondary students. (Section 4310(2) of the ESEA)

Charter management organization means a nonprofit organization that operates or manages a network of charter schools linked by centralized support, operations, and oversight. (Section 4310(3) of the ESEA)

Developer means an individual or group of individuals (including a public or private nonprofit organization), which may include teachers, administrators and other school staff, parents, or other members of the local community in which a charter school project will be carried out. (Section 4310(5) of the ESEA)

Dual or concurrent enrollment program means a program offered by a partnership

between at least one institution of higher education and at least one local educational agency through which a secondary school student who has not graduated from high school with a regular high school diploma is able to enroll in one or more postsecondary courses and earn postsecondary credit that—

(A) Is transferable to the institutions of higher education in the partnership; and
(B) Applies toward completion of a degree or recognized educational credential as described in the Higher Education Act of 1965 (20 U.S.C. 1001 *et seq.*). (Section 8101(15) of the ESEA)

Early college high school means a partnership between at least one local educational agency and at least one institution of higher education that allows participants to simultaneously complete requirements toward earning a regular high school diploma and earn not less than 12 credits that are transferable to the institutions of higher education in the partnership as part of an organized course of study toward a postsecondary degree or credential at no cost to the participant or participant's family. (Section 8101(17) of the ESEA)

Expand, when used with respect to a high-quality charter school, means to significantly increase enrollment or add one or more grades to the high-quality charter school. (Section 4310(7) of the ESEA)

High-quality charter school means a charter school that—

(a) Shows evidence of strong academic results, which may include strong student academic growth, as determined by a State;

(b) Has no significant issues in the areas of student safety, financial and operational management, or statutory or regulatory compliance;

(c) Has demonstrated success in significantly increasing student academic achievement, including graduation rates where applicable, for all students served by the charter school; and

(d) Has demonstrated success in increasing student academic achievement, including graduation rates where applicable, for each of the subgroups of students, as defined in section 1111(c)(2), except that such demonstration is not required in a case in which the number of students in a group is insufficient to yield statistically reliable information or the results would reveal personally identifiable information about an individual student. (Section 4310(8) of the ESEA)

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.*, the active “ingredients” that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes. (34 CFR 77.1)

Replicate, when used with respect to a high-quality charter school, means to open a new charter school, or a new campus of a high-quality charter school, based on the educational model of an existing high-quality charter school, under an existing charter or an additional charter, if permitted or required by State law. (Section 4310(9) of the ESEA)

Selection Criteria: The following selection criteria are from section 4305(b)(4) of the ESEA.

(4) Selection Criteria.—The Secretary shall select eligible entities to receive grants under this subsection, on the basis of the quality of the applications submitted under paragraph (3), after taking into consideration such factors as—

(A) The degree to which the eligible entity has demonstrated success in increasing academic achievement for all students and for each of the subgroups of students described in section 1111(c)(2) attending the charter schools the eligible entity operates or manages;

(B) A determination that the eligible entity has not operated or managed a significant proportion of charter schools that—

(i) Have been closed;

(ii) Have had the school's charter revoked due to problems with statutory or regulatory compliance; or

(iii) Have had the school's affiliation with the eligible entity revoked or terminated, including through voluntary disaffiliation; and

(C) A determination that the eligible entity has not experienced significant problems with statutory or regulatory compliance that could lead to the revocation of a school's charter.

Terms and Conditions: The following terms and conditions are from section 4305(c) of the ESEA.

(c) Terms and Conditions.—Except as otherwise provided, grants awarded under paragraphs (1) and (2) of subsection (a) shall have the same terms and conditions as grants awarded to State entities under section 4303.

[FR Doc. 2018–15977 Filed 7–26–18; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2008–0084; FRL–9981–38—Region 6]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Old Esco Manufacturing Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of intent.

SUMMARY: The Environmental Protection Agency (EPA) Region 6 is issuing a Notice of Intent to Delete the Old Esco Manufacturing Superfund Site (Site) located in Greenville, Texas, from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is

an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Texas, through the Texas Commission on Environmental Quality, have determined that all appropriate response actions under CERCLA, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments must be received by August 27, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–2008–0084, by mail to Brian W. Mueller; U.S. Environmental Protection Agency, Region 6, Superfund Division (6SF–RL), 1445 Ross Avenue, Suite 1200; Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this issue of the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Brian W. Mueller, Remedial Project Manager, U.S. Environmental Protection Agency, Region 6, Superfund Division (6SF–RL), 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733, (214) 665–7167, email: mueller.brian@epa.gov.

SUPPLEMENTARY INFORMATION: In the “Rules and Regulations” section of this issue of the **Federal Register**, we are publishing a direct final Notice of Deletion of Old Esco Manufacturing Superfund Site without prior Notice of Intent to Delete because we view this as a noncontroversial revision and anticipate no adverse comment. We have explained our reasons for this deletion in the preamble to the direct final Notice of Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this deletion action, we will not take further action on this Notice of Intent to Delete. If we receive adverse comment(s), we will withdraw the direct final Notice of Deletion, and it will not take effect. We will, as appropriate, address all public comments in a subsequent final Notice of Deletion based on this Notice of Intent to Delete. We will not institute a second comment period on this Notice of Intent to Delete. Any parties interested in commenting must do so at this time.

For additional information, see the direct final Notice of Deletion which is located in the *Rules* section of this issue of the **Federal Register**.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: July 19, 2018.

Arturo Blanco,

Acting Regional Administrator, Region 6.

[FR Doc. 2018–16121 Filed 7–26–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2003–0010; FRL–9981–25–Region 5]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Peters Cartridge Factory Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notification of intent.

SUMMARY: The Environmental Protection Agency (EPA) Region 5 is issuing a Notice of Intent for Partial Deletion of the Former Process Area (FPA) of the Peters Cartridge Factory Superfund Site (Peters Cartridge Site) located in Kings Mills, Ohio from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Ohio, through the Ohio Environmental Protection Agency (OEPA), have determined that all appropriate response actions at the FPA under CERCLA, other than maintenance, monitoring and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments must be received by August 27, 2018.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–2003–0010, by mail to Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the “Rules and Regulations” section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, Phone: (312) 886–6036, email: cano.randolph@epa.gov.

SUPPLEMENTARY INFORMATION: In the “Rules and Regulations” section of today’s **Federal Register**, we are publishing a direct final Notice of Partial Deletion for the FPA of the Peters Cartridge Site simultaneously with this Notice of Intent for Partial Deletion because EPA views this as a noncontroversial revision and anticipates no adverse comment. We have explained our reasons for this partial deletion in the preamble to the direct final Notice of Partial Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this partial deletion action, we will not take further action on this Notice of Intent for Partial Deletion. If we receive adverse comment(s), we will withdraw the direct final Notice of Partial Deletion and it will not take effect. We will, as appropriate, address all public comments in a subsequent final Notice of Partial Deletion based on this Notice of Intent for Partial Deletion. We will not institute a second comment period on this Notice of Intent for Partial Deletion. Any parties interested in commenting must do so at this time.

For additional information, see the direct final Notice of Partial Deletion which is located in the “Rules and Regulations” section of this **Federal Register**.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757,

3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated July 17, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

[FR Doc. 2018–16122 Filed 7–26–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 36

[WC Docket No. 80–286; FCC 18–99]

Jurisdictional Separations and Referral to the Federal-State Joint Board

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission proposes to extend the freeze of jurisdictional separations category relationships and cost allocation factors for 15 years. The Commission also proposes to provide rate-of-return carriers who elected to freeze their category relationships a time limited opportunity to opt out of that freeze. The Commission invites comment on these proposals, on whether it should modify any other aspects of the separations freeze, and on whether it should alter the scope of its referral to the Federal State Joint Board on Jurisdictional Separations (Joint Board) regarding comprehensive separations reform.

DATES: Comments are due on or before August 27, 2018. Reply comments are due on or before September 10, 2018.

ADDRESSES: You may submit comments identified by WC Docket 80–286, by any of the following methods:

- *Federal Communications Commission’s Website:* <http://apps.fcc.gov/ecfs/>. Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: FCC504@fcc.gov or phone: (202) 418–0530 or TTY: 888–835–5322.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Marvin Sacks, Wireline Competition Bureau, Pricing Policy Division at (202) 418–2017 or via email at marvin.sacks@fcc.gov.

SUPPLEMENTARY INFORMATION: This is summary of the Commission's Further Notice of Proposed Rulemaking (Further Notice), FCC 18–99, released July 18, 2018. A full-text version of the document can be obtained at the following internet address: <https://www.fcc.gov/document/fcc-proposes-extend-jurisdictional-separations-freeze>.

I. Background

A. The Jurisdictional Separations Process

1. Rate-of-return incumbent local exchange carriers (LECs) use their networks and other resources to provide both interstate and intrastate services. To help prevent the recovery of the same costs from both the interstate and intrastate jurisdictions, the Commission's rules require that rate-of-return incumbent LECs divide their costs and revenues between the respective jurisdictions. These "jurisdictional separations" rules were designed to ensure that rate-of-return incumbent LECs apportion the costs of their regulated services between the interstate or intrastate jurisdictions in a manner that reflects the relative use of their networks to provide interstate or intrastate services.

2. Jurisdictional separations is the third step in a four-step regulatory process. First, a rate-of-return carrier records its costs and revenues in various accounts using the Uniform System of Accounts prescribed by the Commission's part 32 rules. Second, the carrier divides the costs and revenues in these accounts between regulated and nonregulated activities in accordance with the Commission's part 64 rules, a step that helps ensure that the costs of nonregulated activities will not be recovered through regulated interstate rates. Third, the carrier separates the regulated costs and revenues between the interstate and intrastate jurisdictions using the Commission's part 36 jurisdictional separations rules. Finally, the carrier apportions the interstate regulated costs among the interexchange services and the rate elements that form the cost basis for its exchange access tariffs. Carriers subject to rate-of-return regulation perform this apportionment in accordance with the Commission's part 69 rules.

3. Rate-of-return incumbent LECs perform annual cost studies that include jurisdictional separations. The jurisdictional separations analysis begins with the categorization of the incumbent LEC's regulated costs and expenses, requiring the incumbent LEC to assign the regulated costs and revenues recorded in its part 32

accounts to various investment, expense, and revenue categories. The incumbent LEC then allocates the costs or revenues in each category between the interstate and intrastate jurisdictions. Amounts in categories that are used exclusively for interstate or intrastate communications are directly assigned to the appropriate jurisdiction. Amounts in categories that support both interstate and intrastate services are allocated between the jurisdictions using relative use factors or fixed allocators.

4. The vast majority of the jurisdictional separations rules were last updated more than 30 years ago and reflect the mix of services and the marketplace circumstances of that time. In 1997, the Commission initiated a proceeding to comprehensively reform those rules to ensure that they reflected the statutory, technological, and marketplace changes that had affected the telecommunications industry. In the *2001 Separations Freeze Order*, the Commission, pursuant to a Joint Board recommendation, froze the part 36 separations rules for a five-year period beginning July 1, 2001, or until the Commission completed comprehensive separations reform, whichever came first ("the separations freeze").

5. More specifically, the Commission adopted a freeze of all part 36 category relationships and allocation factors for price cap carriers, and a freeze of all allocation factors for rate-of-return carriers. It also gave rate-of-return carriers a one-time option to freeze their category relationships, enabling each of these carriers to determine whether such a freeze would be beneficial "based on its own circumstances and investment plans." The election deadline to opt into the category relationships freeze was June 30, 2001.

6. In adopting the separations freeze, the Commission concluded that several issues, including the separations treatment of internet traffic, should be addressed in the context of comprehensive separations reform. The Commission further concluded that the freeze would provide stability and regulatory certainty for incumbent LECs by minimizing any impacts on separations results that might occur due to circumstances not contemplated by the Commission's part 36 rules, such as growth in local competition and the adoption of new technologies. The Commission also found that a freeze of the separations process would reduce regulatory burdens on incumbent LECs during the transition from a regulated monopoly to a deregulated, competitive environment in the local telecommunications marketplace.

7. The Commission has since granted price cap carriers forbearance from the part 36 jurisdictional separations rules. As a result, the separations freeze applies only to rate-of-return carriers, all of whom have frozen allocation factors. Those rate-of-return carriers that chose to freeze their category relationships in 2001 assign investment and expenses within their part 32 accounts to categories using their separations category relationships from 2000, and allocate their categorized costs between the interstate and intrastate jurisdictions using their allocation factors from 2000. This use of "frozen" category relationships and allocation factors frees carriers from conducting separations studies for the duration of the freeze.

B. Declining Applicability of Jurisdictional Separations Results

8. Over the years, the Commission has undertaken initiatives that reduce the role a carrier's costs play in the regulation of rates and in the distribution of high-cost universal service support. Consequently, the significance of jurisdictional separations results has declined. The first of these initiatives was the application of price cap regulation to the largest local exchange carriers, a step that eventually severed the link between separations results and interstate rates for those carriers. Subsequently, as noted above, the Commission forbore from application of the jurisdictional separations rules to price cap incumbent LECs, leaving rate-of-return incumbent LECs as the only carriers required to comply with the separations rules. More recent Commission reforms have eliminated the need for cost data for large portions of rate-of-return carriers' operations as well. Specifically, in 2011, as part of comprehensive reform and modernization of the universal service and intercarrier compensation systems, the Commission adopted rate caps (including a transition to bill-and-keep for certain rate elements) for switched access services for rate-of-return carriers, thereby severing the relationship between cost and switched access rates. In addition, in 2016, the Commission gave rate-of-return carriers the option of receiving high-cost universal service support based on the Alternative-Connect America Cost Model (A–CAM). More than 200 carriers opted to receive A–CAM support, which eliminated the need for those carriers to perform cost studies that required jurisdictional separations to quantify the amount of high-cost support for their common line offerings.

9. As a result of these reforms, rate-of-return carriers now use separations

cost results only for the following limited purposes: (a) Establishing their business data services (special access) rates; (b) calculating interstate common line support for those carriers that have not elected A-CAM support; and (c) calculating subscriber line charge (SLC) levels for the minority of carriers whose SLCs are below the maximum level. The Universal Service Administrative Company (USAC) uses categorization results for calculating high-cost loop support, but without applying jurisdictional allocations. States also use separations results to determine the amount of intrastate universal service support and to calculate regulatory fees, and some states perform rate-of-return ratemaking using intrastate costs.

10. The Commission expects that the use of jurisdictional separations will continue to decline. For example, earlier this year, the Commission adopted a Notice of Proposed Rulemaking that seeks comment on migrating additional rate-of-return carriers to model-based support. In a more recent Notice of Proposed Rulemaking, the Commission proposed to allow A-CAM carriers to transition their business data services offerings from rate-of-return to incentive-based regulation.

C. Procedural History

11. The Commission has extended the separations freeze seven times, with the most recent extension set to expire on December 31, 2018. In adopting and extending the freeze, the Commission has reasoned that the freeze would stabilize and simplify the separations process while the Joint Board and the Commission continued to work on separations reform. In its most recent freeze extension order, the Commission also explained that an extension until December 31, 2018, would provide the Joint Board with sufficient time to consider what effects the Commission's most recent reforms to the high-cost universal service program and intercarrier compensation should have on the separations rules.

12. Since the Commission initiated this proceeding in 1997, the Joint Board—comprised of both state and federal members—has been attempting to develop recommendations for comprehensive reform. In response to the Commission's initial referral, the State Members of the Joint Board filed a report identifying issues they believed should be addressed. Over the years, the State Members filed policy papers setting out options for reform, the Commission or the Joint Board sought comment, and the Joint Board held hearings and meetings to consider the various proposals. Nevertheless, despite

the Commission's repeated extensions of the separations freeze to provide the Joint Board with additional time to issue a Recommended Decision, the Joint Board has not recommended comprehensive reforms.

13. The Commission has twice waived the category relationships freeze to allow individual carriers to adjust the amounts assigned to separations categories to reflect network upgrades. In 2010, the Commission waived that freeze to allow Gila River Telecommunications, Inc., a tribally owned carrier that had upgraded its local loop plant in order to increase the telephone penetration rate in its extremely high-cost service territory, to increase the high-cost loop support it received from the Universal Service Fund (USF) consistent with prior waivers of other universal service rules for carriers serving tribal lands. In 2012, the Wireline Competition Bureau (Bureau) also waived the category relationships freeze to allow Eastex Telephone Cooperative, Inc. (Eastex), a rural cooperative that had upgraded its network with soft switches and fiber to improve its broadband services, to increase its settlements from the National Exchange Carrier Association, Inc. (NECA) special access pool, reducing Eastex's reliance on the USF.

II. Discussion

14. The Commission views jurisdictional separations reform, and the question of whether to extend the separations freeze, in light of its ongoing efforts to transition from rate-of-return to incentive regulation and to eliminate or avoid imposing any unnecessary burdens on carriers. After weighing the likely benefits of extending the freeze against the likely costs of allowing it to end on December 31, 2018, the Commission proposes to extend the separations freeze for 15 years and to provide a time-limited opportunity for carriers that elected the category relationships freeze to opt out of that freeze. The Commission invites comment on these proposals and on the proposed rule changes set forth in Appendix A. The Commission also invites comment on whether it should modify any other aspects of the separations freeze if it adopts the proposal to extend it.

A. Further Extending the Separations Freeze

15. Completion of comprehensive separations reform by the expiration of the freeze on December 31, 2018 is highly unlikely. Most fundamentally, the Commission would prefer not to move forward on separations reform

without a Joint Board recommendation on an approach to such reform, and the Board is not close to reaching a recommendation. As Commissioner Michael O'Rielly, Chairman of the Joint Board, recently observed, "the viewpoints" within the Joint Board "are so vastly different on this complex issue that finding commonality is not going to [be] possible in the near term." Moreover, even if the Joint Board were to offer a recommendation for the Commission's consideration, the Commission would then likely seek comment on that recommendation before issuing an order revising the separations rules. Therefore, as a practical matter, the Commission must choose between extending the separations freeze and allowing long-unused separations rules to take effect on January 1, 2019.

16. The Commission has previously found that letting the freeze expire and allowing largely outmoded separations rules to be reinstated would impose significant burdens on rate-of-return carriers and create undue instability. In extending the freeze in 2017, the Commission explained that reinstating the separations rules would require substantial training and investment by rural incumbent LECs, and could cause significant disruptions in regulated rates, cost recovery, and other operating conditions. The Commission found that the "clear benefits that will result from granting a further extension" of the freeze outweighed any possible harms. It concluded that requiring carriers to reinstate their separations systems "would be unduly burdensome when there is a significant likelihood that there would be no lasting benefit to doing so."

17. The Commission finds its prior analysis compelling and, similarly, that the benefits of an additional extension of the freeze likely would far outweigh any potential harms. The Commission therefore proposes to extend the separations freeze and to direct rate-of-return incumbent LECs to continue to use the same frozen jurisdictional allocation factors. The Commission invites comment on this proposal and on the relative costs and benefits of continuing the separations freeze.

18. In view of these circumstances, the Commission proposes to extend the freeze for 15 years and invites comment on this proposal. The Commission also invites comment on whether a shorter extension would be preferable. The Commission asks that commenters discuss the advantages and disadvantages of a long or short extension period, and provide specific reasons in support of their

recommended timeframes. What effect, if any, would particular extension periods have on ratepayers? Is the Commission's choice of an extension period likely to distort rate levels? Commenters supporting relatively short extension periods should also take into account the time necessary for the Commission and the industry to implement any separations decisions and rule changes.

19. In this regard, the Commission recognizes that the issues before the Joint Board are extremely complex, and the Federal and State members of the Joint Board have not issued a Recommended Decision on comprehensive separations reform in the two decades since the Commission originally proposed such reform. As such, how likely is it that the Joint Board will issue a Recommended Decision on comprehensive separations reform within a relatively short extension period? If consensus within that timeframe is unlikely, should the Commission adopt a relatively long extension? Or should the Commission permanently extend the separations freeze, as USTelecom suggests? Would a relatively long or permanent extension be inconsistent with section 201(b) of the Act's prohibition on unjust and unreasonable charges?

20. The Commission also seeks comment on whether it should change the scope of the issues referred to the Joint Board. In April 2017, the Joint Board issued a public notice seeking comment to refresh the record on issues related to comprehensive, permanent separations reform. Several commenters in response to that public notice recognized the steadily diminishing role of separations results in federal and state regulation, and argued that the Commission should not undertake comprehensive separations reform at the present time because it would be premature, disruptive, and counterproductive. In view of that opposition, should the Commission find that any separations reform in the foreseeable future should be narrowly targeted and change the scope of the issues referred to the Joint Board accordingly? If so, how should the Commission modify the referral to the Joint Board?

B. Allowing Carriers That Elected the Category Relationships Freeze an Opportunity To Change Their Elections

21. The Commission proposes to provide a one-time opportunity for carriers that opted to freeze their category relationships in 2001 to opt out of that freeze, so that they can categorize their costs based on current

circumstances rather than their circumstances in 2000. Presently, rate-of-return carriers in approximately 45 study areas operate under the category relationships freeze. When the Commission granted rate-of-return carriers the opportunity to elect the category relationships freeze, it specified that the freeze would be an interim, "transitional measure" lasting no more than five years. But the freeze has now lasted 17 years, and carriers that elected it are prohibited from withdrawing from their elections. Many of these carriers have since invested in network upgrades or are considering future upgrades. As a result of the category relationships freeze, these carriers may be unable to recover the costs of those investments from the ratepayers that will benefit from those upgrades, or from the USF. Consequently, these carriers may lack incentives to improve service and deploy advanced technologies like broadband for their customers. The Commission therefore proposes and invites comment on allowing carriers to opt out of the category relationships freeze. What are the costs and benefits of this proposal?

22. In the past, commenters have urged the Commission to allow carriers that elected the category relationships freeze to unfreeze those relationships. For example, ITTA points out that the Commission originally allowed rate-of-return carriers the flexibility to decide whether or not to freeze their category relationships because those carriers' size and investment patterns vary widely. ITTA argues that the Commission should provide these carriers with the flexibility to unfreeze their category relationships for similar reasons. ITTA explains that some carriers with frozen category relationships "will embrace the opportunity to more accurately allocate their investment," while others "will find reinstating their separations systems unduly burdensome." Moss Adams, NTCA, WTA, and USTelecom argue that unfreezing category relationships will allow carriers to assign costs in a manner that reflects how they offer services today and will enable carriers to take greater advantage of universal service funds that support broadband deployment. The Commission invites commenters to elaborate on why the Commission should allow carriers to unfreeze their category relationships. The Commission also seeks input from any commenters that oppose such action. The Commission seeks input on the costs and benefits of permitting carriers to unfreeze their category relationships—

both from carriers that believe they may benefit from an unfreeze and from carriers, if applicable, that believe unfreezing category relationships would not be beneficial for them.

23. In the years since 2000, many, and perhaps all, carriers subject to the category relationships freeze have made substantial investments to modernize their networks and to improve and expand their service offerings. In at least some instances, these investments are more weighted toward business data services, and away from switched access and common line categories, than the carriers' investments were as of 2000. If that is the case, under the category relationships freeze, disproportionate percentages of those carriers' investments are currently assigned to the common line and switched access categories. Are carriers that elected the category relationships freeze consequently unable to recover the costs of network upgrades from their business data services customers and from NECA's special access pool? If so, how does that circumstance impact their switched access rates? How many carriers subject to the category relationships freeze face these conditions, and how many would benefit from opting out of that freeze?

24. The Commission asks commenters to specifically describe their current network investments compared to their investments in 2000 and to specify how their category relationships would change without a freeze. The Commission invites comment on what effect allowing carriers to opt out of the category relationships freeze would have on future investment. For example, would lifting the category relationships freeze promote greater investment in newer technologies and increased broadband deployment, and if so, how? The Commission also seeks input on what impact unfreezing category relationships would have on how carriers recover their costs. For example, if carriers are allowed to update their network cost assignments to more accurately reflect the services they provide today, how would the pricing of services—particularly business data services—be affected? Would carriers seek to better align their rates for specific services with the underlying costs of those services? Would opting out of the freeze result in more efficient pricing, and how would it affect consumers in terms of service and pricing?

25. Allowing carriers to opt out of the category relationships freeze will necessarily shift costs between jurisdictions and among access elements, and may affect the universal

service funding the carrier receives. The Commission asks parties to describe the direction of these changes and, where possible, to quantify them. More specifically, to what extent would unfreezing carriers' category relationships shift costs from the intrastate jurisdiction to the interstate jurisdiction, and from common line to special access? In the event of such shifts, what would be the effect on the carriers' receipt of CAF BLS and other universal service funding?

26. The Commission seeks comment on whether it should impose measures to prevent carriers that opt out of the category relationships freeze from double-recovering costs through end-user charges and Connect America Fund intercarrier compensation (CAF ICC) support. If so, what specific measures should it adopt? For example, in the *Eastex Waiver Order*, the Bureau addressed the concern that a rate-of-return carrier might receive an inappropriate amount of universal service funding or double-recover its costs when its category relationships were unfrozen. This situation could occur because, under the *USF/ICC Transformation Order*, a carrier can in certain situations recover its reduced intercarrier compensation revenue through CAF ICC support based on a cost recovery mechanism that is tied to a carrier's interstate switched access revenue requirement for October 1, 2010 through September 30, 2011 (FY2011). Thus, there is a risk that, as a carrier moves costs from the interstate switched access category into different categories, it could double-recover the same costs—once through CAF ICC support and again through special access rates and related NECA settlements.

27. To prevent such a double recovery, in granting a waiver of the category relationships freeze to Eastex, the Bureau required Eastex to recalculate its 2011 Rate-of-Return Carrier Base Period Revenue (BPR) using actual, unfrozen categories and to file a revised interstate switched access revenue requirement. The Bureau expected that the recalculation would reduce the interstate switched access revenue requirement included in Eastex's BPR and shift costs from interstate common line to interstate special access. The Bureau concluded that removing "an amount representative of the FY2011 interstate revenue attributable to the investment being shifted from interstate switched access to other categories" from possible recovery through CAF ICC support would protect consumers and the USF.

28. Consistent with this precedent, should the Commission require any

carrier that opts out of the category relationships freeze to recalculate its BPR using unfrozen category relationships and to file a revised interstate switched access revenue requirement with the Commission? If the Commission requires carriers that are allowed to unfreeze their category relationships to recalculate their BPRs, it proposes to use 2011 cost study data because those are the most recent data that do not reflect the effects of the *USF/ICC Transformation Order*. The Commission invites parties to comment on this approach. While some carriers may have the necessary data to perform the study, others may not. For those that do not, the Commission invites parties to propose an alternative means of estimating the BPR adjustment that should be made.

29. To the extent that a carrier's BPR is adjusted by the preceding calculations, should the Commission require that the carrier adjust its interstate switched access rate cap by a percentage amount equal to the adjustment made to the interstate projected revenue requirement component of the BPR? The carrier would then revise its rates to reflect the transitions mandated by the *USF/ICC Transformation Order* as of the date of the next annual access tariff filing. The Commission invites parties to comment on this approach and on whether it would provide a reasonable method for eliminating potential double recoveries resulting from unfreezing category relationships.

30. In the interest of simplicity, the Commission proposes to allow carriers subject to the category relationships freeze a single opportunity to unfreeze their frozen category relationships. The Commission seeks comment on that approach. If the Commission provides this one-time opportunity, should it require that carriers electing to unfreeze their category relationships make conforming changes to their tariffs effective on July 1, 2019? If so, should it require that carriers with frozen categories notify the Commission and NECA (if a carrier participates in NECA's special access pool) by March 1, 2019 of their decisions to opt out of the category relationships freeze? Would a July 1, 2019 effective date provide carriers with sufficient time to implement any changes needed to update category relationships?

31. In the alternative, should the Commission allow carriers subject to the category relationships freeze to unfreeze their category relationships at any date they choose in the future? What would be the benefits and drawbacks of such an approach? Should the Commission

allow a carrier presently subject to the category relationships freeze that opts to unfreeze its category relationships to refreeze those relationships at some future date? What would be the costs and benefits of this approach?

32. Instead of *allowing* carriers the option of unfreezing their category relationships, should the Commission *require* all rate-of-return carriers that currently operate under the category relationships freeze to unfreeze their category relationships? What would be the impact of lifting the category relationships freeze for all carriers that elected the relationships freeze in 2001? Would it significantly increase the accuracy of separations results and, if so, would any benefits from that increased accuracy outweigh any costs that a mandatory unfreeze would impose?

33. In adopting the separations freeze in 2001, the Commission anticipated that its "waiver process [would] provide a mechanism for relief when special circumstances warrant a deviation from the freeze." The Commission previously granted two petitions for waiver to allow carriers to withdraw from the category relationships freeze and have two waiver requests pending. If the Commission does not allow all affected carriers to unfreeze their category relationships in this rulemaking, would other carriers subject to this relationships freeze feel the need to seek relief of the freeze through the waiver process? Are there particular facts or circumstances that the Commission should consider in assessing whether a carrier has demonstrated sufficient "good cause" to justify a waiver under the Commission's rules that would allow a carrier to unfreeze its category relationships?

34. The Commission also seeks input on whether there is any reason to allow carriers not currently subject to the category relationships freeze to elect to freeze their categories. The Commission asks carriers to provide detailed information about any costs they encounter in categorizing their regulated costs and revenues as well as information on how their category relationships have changed over time. These carriers should address whether the benefits from eliminating those administrative costs would outweigh any loss in the accuracy of separations results that would arise from freezing their category relationships. Further, the Commission seeks input on what base period of data carriers should use for their calculations if it allows them to elect to freeze their category relationships.

35. If the Commission allows carriers not currently subject to the category relationships freeze to elect to freeze their categories, what opportunities should the Commission provide for unfreezing them going forward? What procedures should the Commission adopt if it decides to allow changes in elections? For instance, should the Commission allow carriers to change their elections on a periodic basis—for example, every three years? Finally, the Commission seeks comment on whether it should allow carriers that opt to unfreeze their category relationships the option to update those category relationships and then refreeze them immediately or at some later date. What would be the costs and benefits to the carriers and to the public of allowing carriers to unfreeze and then refreeze their category relationships?

C. Changes to Other Aspects of the Separations Freeze

36. If the Commission adopts its proposal to extend the separations freeze, are there any other aspects of the freeze it should modify? The Commission asks commenters to identify any specific problems with the freeze as well as potential solutions.

37. In the *2001 Separations Freeze Order*, the Commission required that all rate-of-return incumbent LECs apportion their categorized costs using their allocation factors for the year 2000. Should the Commission allow, or require, rate-of-return LECs to reset their jurisdictional allocation factors using current data? The Commission asks commenters to describe in detail the benefits and costs of such actions. The Commission invites comment on whether the Commission should allow, or require, carriers to refreeze their jurisdictional allocation factors once they are reset. The Commission also seeks comment on how any reset of jurisdictional allocation factors should be implemented, including providing information regarding timeframes, deadlines, period of data to be used, and any other related details.

D. Effect on Small Entities

38. The Commission seeks comment on the effect that its proposals to extend the separations freeze and to allow rate-of-return carriers to opt out of the category relationships freeze would have on small entities, and whether any rules that the Commission adopts should apply differently to small entities. The Commission seeks comment on the costs and burdens of these proposals on small incumbent LECs and whether these proposals would disproportionately affect specific

types of carriers or ratepayers. The Commission also seeks input on the effect, if any, on small entities of any other aspects of the separations freeze that it inquires about in this Further Notice.

III. Procedural Matters

A. Deadlines and Filing Procedures

39. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document in CC Docket No. 80–286. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS).

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: <http://apps.fcc.gov/ecfs/>.

- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary: Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554.

- *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

40. *Ex Parte Requirements.* This proceeding shall be treated as a “permit-

but-disclose” proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (e.g., .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

B. Initial Regulatory Flexibility Analysis

41. Pursuant to the Regulatory Flexibility Act (RFA), the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities of the policies and actions considered in this Further Notice. The text of the IRFA is set forth in Appendix B of the Further Notice. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comment provided in the Further Notice. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of

this Further Notice of Proposed Rulemaking, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

C. Paperwork Reduction Act

42. This document may contain proposed new or modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, the Commission seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

IV. Initial Regulatory Flexibility Analysis

A. Need for, and Objectives of, the Proposed Rules

43. The vast majority of the part 36 jurisdictional separations rules were last updated more than 30 years ago. In 1997, the Commission initiated a proceeding to comprehensively reform those rules in light of the statutory, technological, and marketplace changes that had affected the telecommunications industry. In 2001, the Commission, pursuant to a recommendation by the Federal-State Joint Board on Jurisdictional Separations (Joint Board), froze the part 36 separations rules for a five-year period beginning July 1, 2001, or until the Commission completed comprehensive separations reform, whichever came first.

44. The Commission has extended the freeze seven times, with the most recent extension set to expire on December 31, 2018. The Commission would prefer not to move forward on separations reform without a Joint Board recommendation on an approach to such reform, and the Board is not close to reaching a recommendation. Therefore, as a practical matter, completion of comprehensive separations reform by the expiration of the freeze on December 31, 2018 is highly unlikely, and the Commission must choose between extending the separations freeze and allowing long-unused separations rules to take effect on January 1, 2019.

45. Because the Commission expects that the benefits of further extending the jurisdictional separations freeze likely outweigh the costs of allowing it to end,

the Commission in this Further Notice proposes to extend the freeze for 15 years, and invites comment on whether a shorter extension would be preferable. The Commission also seeks comment on whether it should alter the scope of the referral to the Joint Board regarding comprehensive separations reform. The Commission also proposes to permit rate-of-return carriers that elected to freeze their category relationships in 2001 to opt out of this freeze, and it seeks comment on that proposal.

B. Legal Basis

46. The legal basis for the Further Notice is contained in sections 1, 4(i) and (j), 205, 220, 221(c), 254, 303(r), 403, and 410 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i) and (j), 205, 220, 221(c), 254, 303(r), 403, 410, and section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 1302.

C. Description and Estimate of the Number of Small Entities to Which Rules May Apply

47. The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term “small entity” as having the same meaning as the terms “small business,” “small organization,” and “small governmental jurisdiction.” In addition, the term “small business” has the same meaning as the term “small business concern” under the Small Business Act. A “small business concern” is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA. Nationwide, there are 28.8 million small businesses, according to the SBA.

48. Incumbent Local Exchange Carriers. Neither the Commission nor the SBA has developed a small business size standard specifically for providers of incumbent local exchange services. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under the SBA definition, a carrier is small if it has 1,500 or fewer employees. According to the FCC’s Telephone Trends Report data, 1,307 incumbent local exchange carriers (LECs) reported that they were engaged in the provision of local exchange services. Of these 1,307 carriers, an estimated 1,006 have 1,500 or fewer employees and 301 have more than 1,500 employees. Consequently, the Commission estimates that most incumbent LECs are small entities that may be affected by

the rules and policies addressed in this Further Notice.

49. The Commission has included small incumbent LECs in this RFA analysis. As noted above, a “small business” under the RFA is one that, *inter alia*, meets the pertinent small business size standard (*e.g.*, a telephone communications business having 1,500 or fewer employees), and “is not dominant in its field of operation.” The SBA’s Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not “national” in scope. Because the Commission’s proposals concerning the Part 36 separations process will affect all rate-of-return incumbent LECs providing interstate services, some entities employing 1,500 or fewer employees may be affected by the proposals made in this Further Notice. The Commission has therefore included small incumbent LECs in this RFA analysis, although it emphasizes that this RFA action has no effect on the Commission’s analyses and determinations in other, non-RFA contexts.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

50. If a rate-of-return carrier were allowed to opt out of the category relationships freeze, it would be able to update its Part 36 category relationships annually by doing new cost studies and then adjusting its rates. The Further Notice elicits comment on whether rates based on the updated relationships should take effect with the July 1, 2019 tariff filing. If so, as part of that filing, rate-of-return carriers will need to explain the new studies in the Description & Justification section and submit the results of these studies in their tariff review plans.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

51. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance and reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from

coverage of the rule, or part thereof, for small entities.

52. The jurisdictional freeze has eliminated the need for all incumbent LECs, including incumbent LECs with 1,500 employees or fewer, to complete certain annual separations studies that otherwise would be required by the Commission's rules. Thus, an extension of this freeze would avoid increasing the administrative burden of regulatory compliance for rate-of-return incumbent LECs, including small incumbent LECs.

53. Presently, rate-of-return carriers in about 45 study areas operate under a category relationships freeze. When the Commission granted rate-of-return carriers the opportunity to elect the category relationships freeze, it specified the freeze would be an interim, "transitional measure" lasting no more than five years. But, the freeze has now lasted 17 years, and carriers that elected it are prohibited from withdrawing from that election. The Commission proposes to grant these carriers the opportunity to opt out of this freeze. The Commission recognizes that the size and investment patterns of these carriers vary widely, and implementation of this proposal would enable an individual carrier to decide for itself if the economic benefits of unfreezing its category relationships outweigh any costs.

54. The Commission seeks comment on the effect of its proposals on small entities, and whether any rules that the Commission adopts should apply differently to small entities. The Commission directs commenters to consider the costs and burdens of these proposals on small incumbent LECs and whether the proposals would disproportionately affect specific types of carriers or ratepayers.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

55. None.

V. Ordering Clauses

56. Accordingly, *it is ordered*, pursuant to sections 1, 4(i) and (j), 205, 220, 221(c), 254, 303(r), 403, and 410 of the Communication Act of 1934, as amended, 47 U.S.C. 151, 154(i) and (j), 205, 220, 221(c), 254, 303(r), 403, 410, and section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 1302, that this Further Notice of Proposed Rulemaking *is adopted*.

57. *It is further ordered*, pursuant to section 220(i) of the Communications Act, 47 U.S.C. 220(i), that notice be given to each state commission of the above rulemaking proceeding, and that

the Secretary *shall serve* a copy of this Further Notice of Proposed Rulemaking on each state commission.

58. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Further Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects for CFR Part 36

Reporting and recordkeeping requirements, Telephone, Uniform system of accounts.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 36 as follows:

PART 36—JURISDICTIONAL SEPARATIONS PROCEDURES; STANDARD PROCEDURES FOR SEPARATING TELECOMMUNICATIONS PROPERTY COSTS, REVENUES, EXPENSES, TAXES AND RESERVES FOR TELECOMMUNICATIONS COMPANIES

■ 1. The authority citation for part 36 is revised to read as follows:

Authority: 47 U.S.C. 151, 154(i) and (j), 205, 220, 221(c), 254, 303(r), 403, 410, and 1302 unless otherwise noted.

■ 2. Amend § 36.3 by revising paragraph (b) to read as follows:

§ 36.3 Freezing of jurisdictional separations category relationships and/or allocation factors.

* * * * *

(b) Effective July 1, 2001, through December 31, 2033, local exchange carriers subject to price cap regulation, pursuant to § 61.41 of this chapter, shall assign costs from the part 32 accounts to the separations categories/sub-categories, as specified herein, based on the percentage relationships of the categorized/sub-categorized costs to their associated part 32 accounts for the twelve month period ending December 31, 2000. If a part 32 account for separations purposes is categorized into more than one category, the percentage relationship among the categories shall be utilized as well. Local exchange carriers that invest in types of telecommunications plant during the period July 1, 2001, through December 31, 2033, for which it had no separations category investment for the

twelve month period ending December 31, 2000, shall assign such investment to separations categories in accordance with the separations procedures in effect as of December 31, 2000. Local exchange carriers not subject to price cap regulation, pursuant to § 61.41 of this chapter, may elect to be subject to the provisions of paragraph (b) of this section. Such election must be made prior to July 1, 2001. Any local exchange carrier that elected to be subject to paragraph (b) of this section may withdraw from that election by notifying the Commission prior to March 1, 2019 of its intent to withdraw from that election, and that withdrawal will be effective as of July 1, 2019. Any local exchange carrier choosing to withdraw from its election under paragraph (b) of this section that participates in an Association tariff, pursuant to § 69.601 *et seq.*, also shall notify the Association prior to March 1, 2019, of such intent. Subject to that one exception, local exchange carriers that previously elected to become subject to paragraph (b) shall not be eligible to withdraw from such regulation for the duration of the freeze.

* * * * *

§ 36.126 [Amended]

■ 2. Amend § 36.126(b)(5) by removing the date "June 30, 2014" and adding in its place "December 31, 2033."

§§ 36.3, 36.123, 36.124, 36.125, 36.126, 36.141, 36.142, 36.152, 36.154, 36.155, 36.156, 36.157, 36.191, 36.212, 36.214, 36.372, 36.374, 36.375, 36.377, 36.378, 36.379, 36.380, 36.381, and 36.382

[Amended]

■ 3. In 47 CFR part 36, remove the date "December 31, 2018" and add in its place everywhere it appears the date "December 31, 2033" in the following places:

- a. Section 36.3(a), (c), (d) introductory text, and (e);
- b. Section 36.123(a)(5) and (6);
- c. Section 36.124(c) and (d);
- d. Section 36.125(h) and (i);
- e. Section 36.126(b)(6), (c)(4), (e)(4), and (f)(2);
- f. Section 36.141(c);
- g. Section 36.142(c);
- h. Section 36.152(d);
- i. Section 36.154(g);
- j. Section 36.155(b);
- k. Section 36.156(c);
- l. Section 36.157(b);
- m. Section 36.191(d);
- n. Section 36.212(c);
- o. Section 36.214(a);
- p. Section 36.372;
- q. Section 36.374(b) and (d);
- r. Section 36.375(b)(4) and (5);
- s. Section 36.377(a) introductory text, (a)(1)(ix), (a)(2)(vii), (a)(3)(vii), (a)(4)(vii), (a)(5)(vii), and (a)(6)(vii);

- t. Section 36.378(b)(1);
- u. Section 36.379(b)(1) and (2);
- v. Section 36.380(d) and (e);
- w. Section 36.381(c) and (d); and
- x. Section 36.382(a)

[FR Doc. 2018–16040 Filed 7–26–18; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180212159–8159–01]

RIN 0648–BH75

Atlantic Highly Migratory Species; Shortfin Mako Shark Management Measures; Proposed Amendment 11

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS is proposing to amend the 2006 Consolidated Atlantic Highly Migratory Species (HMS) Fishery Management Plan (FMP) based on the results of the 2017 stock assessment and a subsequent binding recommendation by the International Commission for the Conservation of Atlantic Tunas (ICCAT) for North Atlantic shortfin mako sharks. The North Atlantic shortfin mako shark stock is overfished and is experiencing overfishing. Consistent with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the Atlantic Tunas Convention Act (ATCA), NMFS is proposing management measures that would reduce fishing mortality on shortfin mako sharks and establish a foundation for rebuilding the shortfin mako shark population consistent with legal requirements. The proposed measures could affect U.S. commercial and recreational fishermen who target and harvest shortfin mako sharks in the Atlantic Ocean, including the Gulf of Mexico and Caribbean Sea by increasing live releases and reducing landings.

DATES: Written comments must be received by October 1, 2018. NMFS will hold six public hearings and an operator-assisted public hearing via conference call and webinar on this proposed rule for Draft Amendment 11 to the 2006 Consolidated HMS FMP (Amendment 11) in August and September 2018. For specific dates and

times see the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2018–0011, by any one of the following methods:

- **Electronic Submission:** Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0011, click the “Comment Now” icon, complete the required fields, and enter or attach your comments.
- **Mail:** Submit written comments to Guý DuBeck, NMFS/SF1, 1315 East-West Highway, National Marine Fisheries Service, SSMC3, Silver Spring, MD 20910.

Instructions: Please include the identifier NOAA–NMFS–2018–0011 when submitting comments. Comments sent by any other method, to any other address or individual, or received after the close of the comment period, may not be considered by NMFS. All comments received are a part of the public record and generally will be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

NMFS will hold six public hearings and one operator-assisted public hearing via conference call and webinar on this proposed rule and Draft Amendment 11. NMFS will hold public hearings in Corpus Christi, TX; Linwood, NJ; Manteo, NC; Morehead City, NC; Gloucester, MA; and St. Petersburg, FL. For specific locations, see the **SUPPLEMENTARY INFORMATION** section of this document.

Copies of the supporting documents—including the draft environmental impact statement (DEIS), Regulatory Impact Review (RIR), Initial Regulatory Flexibility Analysis (IRFA), and the 2006 Consolidated Atlantic HMS FMP and amendments are available from the HMS website at <https://www.fisheries.noaa.gov/topic/atlantic-highly-migratory-species> or by contacting Guý DuBeck at (301) 427–8503.

FOR FURTHER INFORMATION CONTACT: Guý DuBeck or Karyl Brewster-Geisz at (301) 427–8503.

SUPPLEMENTARY INFORMATION:

Background

The North Atlantic shortfin mako stock is managed primarily under the authority of the Magnuson-Stevens Act and also under ATCA. The 2006 Consolidated HMS FMP and its amendments are implemented by regulations at 50 CFR part 635. A brief summary of the background of this proposed rule is provided below. Additional information regarding Atlantic shark management can be found in the DEIS accompanying this proposed rule for Amendment 11, the 2006 Consolidated HMS FMP and its amendments, the annual HMS Stock Assessment and Fishery Evaluation (SAFE) Reports, and online at <https://www.fisheries.noaa.gov/topic/atlantic-highly-migratory-species>.

North Atlantic Shortfin Mako Shark Stock Status and Emergency Interim Final Rule

The North Atlantic shortfin mako shark (*Isurus oxyrinchus*) is a highly migratory species that ranges across the entire North Atlantic Ocean and is caught by numerous countries. The stock is predominantly caught offshore in association with fisheries that primarily target tunas and tuna-like species. While these sharks are a valued component of U.S. recreational and commercial fisheries, U.S. catch represents only approximately 11 percent of the species’ total catch in the North Atlantic by all reporting countries. International measures are, therefore, critical to the species’ effective conservation and management.

In August 2017, ICCAT’s Standing Committee on Research and Statistics (SCRS) conducted a new benchmark stock assessment on the North Atlantic shortfin mako stock. At its November 2017 annual meeting, ICCAT accepted this stock assessment and determined the stock to be overfished, with overfishing occurring. On December 13, 2017, based on this assessment, NMFS issued a status determination finding the stock to be overfished and experiencing overfishing applying domestic criteria. The assessment specifically indicated that biomass (B_{2015}) is substantially less than the biomass at maximum sustainable yield (B_{MSY}) for eight of the nine models used for the assessment ($B_{2015}/B_{MSY} = 0.57 - 0.85$). In the ninth model, spawning stock fecundity (SSF) was less than SSF_{MSY} ($SSF_{2015}/SSF_{MSY} = 0.95$). Additionally, the assessment indicated that fishing mortality (F_{2015}) was greater than F_{MSY} (1.93–4.38), with a combined 90 percent probability from all models

that the population is overfished, with overfishing occurring. This was a change from the 2012 stock assessment that indicated that both the North and South Atlantic stocks of shortfin mako sharks were healthy and the probability of overfishing was low. However, the high uncertainty in past catch estimates and deficiency of some important biological parameters, particularly for the Southern stock, were still obstacles for obtaining reliable estimates of current status of the stocks.

The 2017 assessment estimated that total North Atlantic shortfin mako catches across all ICCAT parties are currently between 3,600 and 4,750 metric ton (mt) per year. The assessment further indicated that such total catches would have to be at or below 1,000 mt (72–79 percent reductions) to prevent further population declines, and total catches of 500 mt or less would be expected to stop overfishing and begin rebuilding the stock. The stock assessment projections indicated that a total allowable catch of 0 mt would produce a greater than 50 percent probability of rebuilding the stock by the year 2040, which is approximately equal to one mean generation time. The stock assessment report stated that while research indicates that post-release survival rates of Atlantic shortfin mako sharks are high (70 percent), the assessment could not determine if requiring live releases alone would reduce landings sufficiently to end overfishing and rebuild the stock. The stock assessment did not evaluate rebuilding times greater than one mean generation time, although shark stocks generally take longer than one mean generation time to rebuild given their slow reproductive biology and other factors.

Based on this information and given that the stock is primarily caught in association with ICCAT fisheries, ICCAT at its November 2017 meeting adopted new management measures for Atlantic shortfin mako in Recommendation 17–08. The measures largely focus on maximizing live releases of Atlantic shortfin mako sharks, allowing retention only in certain limited circumstances, increasing minimum size limits for retention, and improving data collection in ICCAT fisheries. ICCAT stated that the measures in the Recommendation “are expected to prevent the population from decreasing further, stop overfishing and begin to rebuild the stock” and provided for a six-month review. The Recommendation requires ICCAT parties that authorize retention to provide to ICCAT “the amount of North Atlantic shortfin mako caught and

retained on board as well as dead discards during the first six months in 2018 by one month prior to the 2018 Commission annual meeting.” The Recommendation specifies that at its annual meeting in November 2018, ICCAT will review the catches from the first six months of 2018 and decide whether these measures should be modified. In 2019, the SCRS will evaluate the effectiveness of these measures in ending overfishing and beginning to rebuild the stock. The SCRS will also provide rebuilding information that reflects rebuilding timeframes of at least two mean generation times, taking into consideration the slow reproductive biology of sharks and other factors. The Recommendation provides that in 2019, ICCAT will establish a rebuilding plan that will have a high probability of avoiding overfishing and rebuilding the stock to B_{MSY} within a timeframe that takes into account the biology of the stock.

On March 2, 2018, NMFS implemented an interim final rule using emergency authority under the Magnuson-Stevens Act, 16 U.S.C. 1855(c), to quickly implement measures in the HMS recreational and commercial fisheries consistent with Recommendation 17–08. NMFS solicited public comment on that rule through May 7, 2018. *See id.* (allowing extension of rule for not more than 186 days if public has opportunity for comment). The purpose of the emergency interim final rule was to address overfishing and to ensure that the U.S. can provide meaningful information reflective of the new measures to ICCAT for the six-month reporting requirement in the Recommendation (83 FR 8946). Management measures adopted through the interim final rule, and which remain in effect, are as follows:

- Commercial fishermen on vessels deploying pelagic longline gear, which are required to have a functional electronic monitoring system on board under current regulations, must release all live shortfin mako sharks with a minimum of harm, while giving due consideration to the safety of crew members. Commercial fishermen using pelagic longline gear can only retain a shortfin mako shark if it is dead at haulback;
- Commercial fishermen using gear other than pelagic longline commercial gear (*e.g.*, bottom longline, gillnet, handgear, etc.) must release all shortfin mako sharks, whether they are dead or alive; and
- Recreational fishermen (fishermen with HMS Angling or Charter/Headboat permits and fishermen with Atlantic Tunas General category and Swordfish General Commercial permits when participating in a registered HMS tournament) must release any shortfin

mako sharks smaller than the newly-implemented minimum size of 83 inches (210 centimeters (cm)) fork length (FL). This minimum size was an increase from the previous minimum size of 54 inches FL. This measure was different than the separate minimum size limits for males (180 cm FL) and females (210 cm FL) recommended in ICCAT Recommendation 17–08. The ICCAT stock assessment upon which the Recommendation was based had recommended an overall reduction in shortfin mako shark landings (or is it mortality?) for ICCAT parties. Consistent with this, in developing this proposed rule, NMFS analyzed minimum sizes in the context of U.S. fisheries and believes that a single minimum size limit of 83 inches (210 cm) FL is needed to address the U.S. portion of recommended mortality reduction (see ADDRESSES for how to get a copy of the DEIS). Furthermore, confirming the sex of a large and potentially active shortfin mako shark prior to its landing could be challenging for fishermen and may have safety implications. A single minimum size limit for the species is also simpler to implement and enforce.

The emergency measures are initially effective for 180 days (ending on August 29, 2018), and may be extended to March 3, 2019. Once finalized, this rule is intended to replace these emergency measures with long-term measures. A Notice of Intent (NOI) to prepare an EIS for Amendment 11 of the Consolidated HMS FMP was published in the **Federal Register** on March 5, 2018 (83 FR 9255).

Proposed Measures

The objectives of Draft Amendment 11 and this proposed rule are to address overfishing and establish a foundation for rebuilding the North Atlantic shortfin mako shark stock, which ICCAT will adopt in 2019 after obtaining additional scientific information, as set out in Recommendation 17–08. In a DEIS, NMFS considered alternatives to meet the objectives of the Amendment. Given the various objectives, NMFS divided alternatives into the following four broad categories for organizational clarity and to facilitate effective review: Commercial fishery, recreational fishery, monitoring, and rebuilding. As summarized below, NMFS fully considered 29 alternatives within these categories and is preferring five measures, one in the commercial fishery, two in the recreational fishery (each regarding a different regulation type), one regarding monitoring, and one regarding rebuilding the stock, to meet the objectives of the rule and achieve at least a 75 percent reduction in U.S. shortfin mako shark landings consistent with the suggested level of reduction recommended in the stock assessment. The stock assessment recommends this level of reduction throughout the stock’s range, and all

ICCAT parties are committed to take the specified measures to achieve the needed reductions. NMFS' detailed analysis of the alternatives is provided in the DEIS for Draft Amendment 11 (see **ADDRESSES** for how to get a copy of the DEIS) and a summary is provided in the IRFA below. In developing the alternatives, NMFS considered commercial retention restrictions and the 83 inch FL recreational minimum size limit now temporarily in place through the emergency interim final rule, public comments received on that rule, other conservation and management measures that have been implemented in the HMS fisheries since 2008 that have affected shark fisheries or shark bycatch in other fisheries, and public comments received on the Amendment 11 Issues and Options paper, including comments provided at the March 2018 HMS Advisory Panel meeting. In response to public comment on this proposed rule and the DEIS, NMFS may make changes in the final rule by modifying the proposed measures or adopting different or additional measures that were not preferred in this proposed rule.

This proposed rule also includes a minor change to the regulations specific to sharks to provide clarity and consistency throughout the regulations. Specifically, this rule proposes minor changes to § 635.30 (c)(4) to update the regulatory language to reference shark endorsements on permits and to clarify when non-commercial fishermen must retain the head, fins, and tails on a shark carcass.

Commercial Measures

Under this proposed rule, a commercial fisherman on a vessel with a directed or incidental shark limited access permit (LAP) could only retain shortfin mako sharks if the shark is dead at haulback, the vessel is deploying pelagic longline gear, and there is a functional electronic monitoring system on board the vessel (Alternative A2). This proposed measure is the same commercial measure instituted under the emergency interim final rule (83 FR 8946; March 2, 2018). Pelagic longline vessels would be required to promptly release in a manner that causes the least harm any shortfin mako shark that is alive at the time of haulback. Commercial fishermen using gear other than pelagic longline commercial gear (e.g., bottom longline, gillnet, handgear, etc.) would be required to release or discard all shortfin mako sharks, whether they are alive or dead at haulback.

Pelagic longline fishermen rarely target shortfin mako sharks. Instead,

fishermen usually catch shortfin mako sharks incidentally while fishing for valuable target species such as tunas and swordfish. Based on observer data, over 70 percent of the shortfin mako sharks interacted with in the pelagic longline fishery were alive at the vessel. Commercial fishermen using other gear types rarely, if ever, catch shortfin mako sharks. Since 2012, only four shortfin mako shark were observed in the bottom longline shark fishery and none were observed in the gillnet shark fishery. Combining live releases in the pelagic longline fishery and prohibiting the minimal landings from other commercial gears, NMFS expects this alternative to result in reductions in U.S. commercial landings of shortfin mako sharks by approximately 75 percent. Therefore, implementing this measure is anticipated to have direct short- and long-term minor, beneficial ecological impacts.

In addition to this preferred commercial alternative, NMFS also considered a No Action (Alternative A1) which would maintain the regulations before the emergency rule went into place (given that the emergency rule is an interim rule that will expire), along with alternatives that would modify the commercial retention restrictions (Alternative A3); use electronic monitoring and/or observers to verify the status of boarded sharks and compliance with the size limit (Alternatives A4 and A5); and prohibit commercial retention (Alternative A6). These alternatives are not preferred at this time. The No Action alternative (Alternative A1) would not implement any new management measures and thus would not reduce shortfin mako shark mortality as needed to end overfishing and begin rebuilding the stock. The alternative that allows commercial fishermen to opt in or out of an electronic monitoring program (Alternative A3) for shortfin mako sharks would be an additional burden on the fishermen that would not have any measurable conservation or management benefits. The program would also be complicated to administer and would create two separate data streams from within the fleet, as some vessels and catch would be compared and analyzed differently due to different regulatory restrictions. The alternative that would use electronic monitoring and/or observers to verify the status of boarded sharks (live or dead) or compliance with any size limit (Alternatives A4 and A5) would place more restrictive limits on fishermen, particularly pelagic longline fishermen, than allowing retention of

shortfin mako sharks that are dead at haulback under the preferred alternative, which would achieve the suggested mortality reduction without such restrictions. The alternative prohibiting commercial retention (Alternative A6) could disadvantage U.S. fishermen compared to fishermen in other ICCAT nations that implement the ICCAT recommendation verbatim. This alternative also would cause more negative economic impacts when compared to the preferred alternative, which would achieve the suggested mortality reduction.

Recreational Measures

NMFS is proposing two measures for the recreational fishery for sharks. Under the first proposed measure (Alternative B3), HMS recreational fishermen could only land shortfin mako sharks, male or female, that are at least 83 inches fork length (210 cm FL). As with the commercial alternative, this alternative matches the management measure implemented in the emergency interim final rule (83 FR 8946; March 2, 2018). According to length composition information from the Large Pelagics Survey, this recreational minimum size would reduce the number of shortfin mako sharks landed by approximately 83 percent in the HMS recreational fishery and would reduce the weight of landings by at least 68 percent. It is likely that the reductions in landings under this alternative would be significantly greater than what is estimated in this proposed rule and the DEIS, as the number of recreational trips targeting shortfin mako sharks would likely decrease substantially given the large increase in the overall size limit and the smaller minimum size limit (54 inches FL for other shark species). Therefore, implementing this measure is anticipated to have direct short- and long-term minor, beneficial ecological impacts.

The second proposed measure (Alternative B9) would require the use of non-offset, non-stainless steel circle hooks when fishing recreationally for sharks in federal waters. The current regulatory requirement for such hooks applies to shark fishing in federal waters south of 41°43' N latitude (near Chatham, Massachusetts), as implemented in Amendment 5b to the 2006 Consolidated HMS FMP. As mentioned in more detail in the DEIS, circle hooks are a bycatch mortality mitigation tool that have shown promise in a number of fisheries for various species including sharks. Most evidence suggests that circle hooks reduce shark mortality rates at-vessel and post-release without reducing catchability of target

species compared to J-hooks, although the reduction in mortality rate varies by species, gear configuration, bait, and other factors. By design, circle hooks tend to hook sharks in the jaw rather than in the throat or gut (deep-hooking), thereby reducing injury and associated mortality.

For shortfin mako sharks specifically, research shows that the use of circle hooks reduces gut-hooking and increases post-release survival. French et al. (2015) examined the effects of recreational fishing techniques, including hook type, on shortfin mako sharks and found that circle hooks were more likely to hook shortfin mako sharks in the jaw compared to J-hooks. In the study, circle hooks were most likely to hook in the jaw (83 percent of the time) while J-hooks hooked in the jaw only 20 percent of the time but in the throat or gut 60 percent of the time. Jaw-hooking is correlated with increased odds of post release survival. Therefore, implementing this measure is anticipated to have direct short- and long-term minor, beneficial ecological impacts.

In addition to the proposed measure, NMFS also considered No Action (Alternative B1) which would maintain the regulations before the emergency rule went into place, along with alternatives that would prohibit recreational retention of shortfin mako sharks (Alternative B10); modify the recreational size limit by sex and seasonal retention or slot limits (Alternatives B2, B4, B5, B6, and B7); and establish a recreational tagging program (Alternative B8). A number of alternatives that were considered and/or commented on during the development of this action are not preferred at this time because they would complicate the regulations for fishermen and not meet the scientific advice for shortfin mako mortality reduction as well as the preferred alternatives. The no action alternative (Alternative B1) would not implement any new management measures and not reduce the shortfin mako shark mortality as needed to end overfishing and begin rebuilding the stock. The alternatives that would modify the recreational size limit by sex and seasonal retention or slot limits (Alternatives B2, B4, B5, B6, and B7) would not meet the objectives of this action as well as the preferred alternatives, and they would add unnecessary complexity to the recreational regulations. The alternative that would establish a landings tag program (Alternative B8) could increase the potential landings of shortfin mako sharks and cause unnecessary administrative burden in managing such

a program. The alternative that considered prohibiting recreational retention entirely would be unnecessarily restrictive, have little effect on ending overfishing, and disadvantage U.S. fishermen compared to fishermen in other ICCAT nations that implement the ICCAT recommendation verbatim, which requires less restrictive measures.

Monitoring Measures

NMFS considered alternatives that would require mandatory reporting on vessel monitoring systems and mandatory reporting of recreational catches. However, after considering these alternatives, NMFS is proposing the No Action alternative (Alternative C1) in relation to monitoring measures. This preferred alternative would make no changes to the current reporting requirements applicable to shortfin mako sharks in HMS fisheries, likely resulting in direct, short- and long-term, neutral ecological impacts. HMS commercial fishermen would continue to report shortfin mako catches through vessel logbooks along with dealer reporting of landings and electronic monitoring systems would be used to verify that the shortfin mako sharks were dead at haulback. HMS recreational anglers fishing from Maine to Virginia would continue to be required to report shortfin mako shark landings and releases if intercepted by the Large Pelagic Survey, and data would continue to be collected on shortfin mako shark catches by the Access Point Angler Intercept Survey, which is part of the Marine Recreational Information Program. Thus, no additional reporting requirements would be placed on HMS Angling and HMS Charter/Headboat permit holders who land shortfin mako sharks on non-tournament trips. Tournament operators would continue to be required to report landings associated with shark tournaments if their tournaments are selected for reporting.

ICCAT's SCRS recommended that member nations strengthen their monitoring and data collection efforts to monitor the future status of this stock. Consistent with the SCRS recommendation, NMFS plans to select shark tournaments for reporting using existing regulations and authorities. The regulations at 50 CFR 635.5(d) require Atlantic HMS tournament operators to register their tournaments with NMFS, and authorize NMFS to select any HMS tournaments for reporting. Currently, NMFS only selects billfish and swordfish tournaments for reporting; however in their reports, those tournaments report catches of all HMS

including sharks. Thus some, but not all, shark catch information from selected billfish and swordfish tournaments are already being collected. The tournament registration category of "pelagic shark" (which includes shortfin mako shark) makes up 95 percent of all shark tournaments and because information from the remaining 5 percent of shark tournaments will be useful for management of non-pelagic sharks, NMFS intends to select all shark tournaments for reporting. Therefore, Alternative C1, the No Action alternative, in combination with selecting all shark tournaments for reporting (which does not require any new regulations) is anticipated to have neutral ecological impacts.

In addition to the No Action (Alternative C1), NMFS also considered alternatives that would require mandatory reporting on vessel monitoring systems (Alternative C2) and mandatory reporting of recreational catches (Alternative C3). A number of alternatives that were considered and/or commented on during the development of this action are not preferred at this time because the current reporting requirements for all HMS commercial vessels are sufficient to meet the purpose and need of this action and additional potential measures would place undue burden on recreational fishermen and potentially create enforcement issues. The alternative that would implement mandatory reporting on the vessel monitoring systems (Alternative C2) would unnecessarily increase burden to HMS commercial vessels that already report in other ways (vessel logbooks, dealer reports of landings and electronic monitoring system) that are sufficient vehicles for improving data collection for shortfin mako sharks. The alternative that would implement mandatory reporting of recreational catches (Alternative C3) would unnecessarily increase the burden on recreational fishermen and monitoring of catches and compliance by NMFS because NMFS estimates of shortfin mako sharks in the recreational fishery currently have relatively high precision, as evidenced by the low percent standard error rates in the Large Pelagic Survey.

Rebuilding Measures

Under the proposed measure (Alternative D3), NMFS would take action at the international level through ICCAT to develop a rebuilding plan for shortfin mako shark stock. As part of this, NMFS would promote Magnuson-Stevens Act's rebuilding provisions and approaches and other relevant provisions of the Act. See 16 U.S.C.

1812(c). This rebuilding plan would encompass the objectives set forth by ICCAT based on new scientific advice from the SCRS, which is currently scheduled to be available in 2019. Under this alternative, NMFS would continue to implement the new management measures adopted through this rulemaking for North Atlantic shortfin mako sharks in United States fisheries based on ICCAT Recommendation 17–08. Any future international management recommendations adopted by ICCAT for shortfin mako sharks would be implemented domestically. Currently, the United States contributes only 11 percent of the mortality for North Atlantic shortfin mako sharks and domestic reductions of shortfin mako shark mortality alone could not end overfishing of the entire North Atlantic stock or effectively rebuild the stock. Therefore, NMFS will continue to take action at the international level through ICCAT, the relevant international fishery management organizations. Through this process, all ICCAT members fishing on the stock participate in the establishment of effective conservation and management measures to end overfishing of and rebuild shortfin mako sharks. In the long-term, any management recommendations adopted at the international level to end overfishing of shortfin mako sharks and rebuild the stock could have direct, moderate beneficial ecological impacts on the North Atlantic shortfin mako shark population by reducing overall mortality of shortfin mako sharks and rebuilding the stock. As an active member of ICCAT, the United States will participate and advocate for an effective rebuilding plan and continue to work through ICCAT on implementation and enforcement of effective conservation and management measures to end overfishing.

In addition to Alternative D3, NMFS also considered No Action (Alternative D1) and alternatives that would

establish a domestic rebuilding plan without ICCAT (Alternative D2); establish a species-specific quota if established by ICCAT (Alternative D4); implement area management if established by ICCAT (Alternative D5); and bycatch caps (Alternative D6). The no action alternative would cause no rebuilding plan to be established. Alternative D2 (domestic rebuilding plan without ICCAT) would not be effective given the stock's range and the fact that the United States catches are only a small part of catches Atlantic-wide. Thus, this alternative would allow the stock to continue to be overfished, with overfishing continuing to occur. Given that U.S. catches of shortfin mako are small, Alternative D4 considers potential impacts of a shortfin mako shark quota if established by ICCAT as opposed to a unilateral U.S. quota. Alternative D4 is not preferred at this time, because ICCAT does not have a total allowable catch for shortfin mako shark, but instead, has measures aimed at reducing mortality and a six-month review to determine if further measures are needed. Alternative D5 (area management) is also not preferred at this time, because ICCAT has not adopted, and does not have scientific information yet to support, such a measure. The current ICCAT Recommendation calls on SCRS to provide additional scientific advice in 2019 that takes into account a spatial/temporal analysis of North Atlantic shortfin mako shark catches in order to identify areas with high interactions. Alternative D6 (bycatch caps) is not preferred, because U.S. catches of shortfin mako are small thus unilateral U.S. bycatch caps will not address overfishing and rebuilding. This alternative would thus have more economic impacts than the preferred alternative without achieving the purpose and need of the action and would unfairly disadvantage U.S. fishermen, as ICCAT currently does not require bycatch caps.

Request for Comments

NMFS is requesting comments on the alternatives and analyses described in this proposed rule and contained in the DEIS, IRFA, and RIR for Draft Amendment 11. Comments may be submitted via <http://www.regulations.gov> or mail. Comments may also be submitted at a public hearing (see Public Hearings and Special Accommodations below). We solicit comments on this proposed rule by October 1, 2018 (see **DATES** and **ADDRESSES**).

Public Hearings

Comments on this proposed rule may be submitted via <http://www.regulations.gov> or mail and comments may also be submitted at a public hearing. NMFS solicits comments on this proposed rule by October 1, 2018. During the comment period, NMFS will hold six public hearings and one operator-assisted public hearing via conference call and webinar for this proposed rule and draft Amendment 11. The hearing locations will be physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Guý DuBeck at 301–427–8503, at least 7 days prior to the meeting. NMFS has also asked to present information on the proposed rule and draft Amendment 11 to the Caribbean, Gulf of Mexico, South Atlantic, Mid-Atlantic, and New England Fishery Management Councils, and the Atlantic and Gulf of Mexico States Marine Fisheries Commissions at their meetings during the public comment period. Please see their meeting notices for dates, times, and locations. In addition, NMFS will present at the HMS Advisory Panel meeting in September, to discuss this rulemaking. NMFS will announce the location and times of HMS Advisory Panel meeting in a future **Federal Register** notice.

TABLE 1—DATES, TIMES, AND LOCATIONS OF UPCOMING PUBLIC HEARINGS AND CONFERENCE CALL

Venue	Date/time	Meeting location	Location contact information
Public Hearing	August 22, 2018, 5 p.m.–8 p.m.	Corpus Christi, TX	Dr. Clotilde Garcia Public Library, 5930 Brockhampton Street, Corpus Christi, TX 78414.
Public Hearing	August 23, 2018, 5 p.m.–8 p.m.	Linwood, NJ	Linwood Public Library, 301 Davis Avenue, Linwood, NJ 08211.
Public Hearing	August 28, 2018, 5 p.m.–8 p.m.	Manteo, NC	Commissioners Meeting Room, Dare County Administration Building, 954 Marshall C. Collins Drive, Manteo, NC 27954.
Public Hearing	August 29, 2018, 5 p.m.–8 p.m.	Morehead City, NC	NCDMF Central District Office, 5285 Highway 70 West, Morehead City, NC 28557.
Public Hearing	August 30, 2018, 5 p.m.–8 p.m.	Gloucester, MA	National Marine Fisheries Service, Grater Atlantic Regional Office, 55 Great Republic Drive, Gloucester, MA 01930.

TABLE 1—DATES, TIMES, AND LOCATIONS OF UPCOMING PUBLIC HEARINGS AND CONFERENCE CALL—Continued

Venue	Date/time	Meeting location	Location contact information
Public Hearing	August 30, 2018, 5 p.m.–8 p.m.	St. Petersburg, FL	National Marine Fisheries Service, Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.
Conference call	September 12, 2018, 2 p.m.–4 p.m.	To participate in conference call, call: (888) 831–4306, Passcode: 2693278, To participate in webinar, RSVP at: https://noaaevents2.webex.com/noaaevents2/onstage/g.php?MTID=e64dda334375685e91c704ca0a5e9882f , A confirmation email with webinar log-in information will be sent after RSVP is registered.

The public is reminded that NMFS expects participants at the public hearings to conduct themselves appropriately. At the beginning of each public hearing, a representative of NMFS will explain the ground rules (*e.g.*, alcohol is prohibited from the hearing room; attendees will be called to give their comments in the order in which they registered to speak; each attendee will have an equal amount of time to speak; and attendees should not interrupt one another). At the beginning of the conference call, the moderator will explain how the conference call will be conducted and how and when attendees can provide comments. The NMFS representative will attempt to structure the meeting so that all attending members of the public will be able to comment, if they so choose, regardless of the controversial nature of the subject(s). Attendees are expected to respect the ground rules, and, if they do not, they may be asked to leave the hearing or may not be allowed to speak during the conference call.

Classification

Pursuant to the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that the proposed rule is consistent with the 2006 Consolidated HMS FMP and its amendments, other provisions of the Magnuson-Stevens Act, ATCA, and other applicable law, subject to further consideration after public comment.

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

NMFS prepared a DEIS for this proposed rule that discusses the impact on the environment that would result from this rule. A copy of the DEIS is available from NMFS (see **ADDRESSES**). The Notice of Availability of the DEIS is publishing in the **Federal Register** on the same day as this proposed rule. A summary of the impacts of the alternatives considered is described above.

Regulatory Flexibility Act

An IRFA was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A summary of the analysis follows. A copy of this analysis is available from NMFS (see **ADDRESSES**).

Section 603(b)(1) requires Agencies to describe the reasons why the action is being considered. The purpose of Amendment 11 is to develop and implement management measures to address overfishing and take steps towards rebuilding the North Atlantic shortfin mako shark stock. Consistent with the provisions of the Magnuson-Stevens Act and ATCA, NMFS proposes to modify the 2006 Atlantic HMS FMP in response to the stock status determination for shortfin mako sharks and the subsequent ICCAT Recommendation (17–08).

Section 603(b)(2) of the RFA requires Agencies to state the objective of, and legal basis for the proposed action. (See Chapter 1 of the DEIS for a full description of the objectives of this action.) Consistent with the provisions of the Magnuson-Stevens Act and ATCA, NMFS proposes to amend the 2006 Atlantic HMS FMP in response to the stock status determination for shortfin mako sharks and the subsequent ICCAT Recommendation (17–08). NMFS has identified the following objectives with regard to this proposed action:

- Address overfishing of shortfin mako sharks;
- Develop and implement management measures consistent with ICCAT Recommendation 17–08; and
- Take steps towards rebuilding the shortfin mako shark stock pending planned development of the ICCAT rebuilding plan, which is necessarily to effectively address stock rebuilding across its range

Section 603(b)(3) of the RFA requires Agencies to provide an estimate of the number of small entities to which the rule would apply. The Small Business

Administration (SBA) has established size criteria for all major industry sectors in the United States, including fish harvesters. Provision is made under the SBA's regulations for an agency to develop its own industry-specific size standards after consultation with SBA Office of Advocacy and an opportunity for public comment (see 13 CFR 121.903(c)). Under this provision, NMFS may establish size standards that differ from those established by the SBA Office of Size Standards, but only for use by NMFS and only for the purpose of conducting an analysis of economic effects in fulfillment of the agency's obligations under the RFA. To utilize this provision, NMFS must publish such size standards in the **Federal Register**, which NMFS did on December 29, 2015 (80 FR 81194, December 29, 2015). In this final rule effective on July 1, 2016, NMFS established a small business size standard of \$11 million in annual gross receipts for all businesses in the commercial fishing industry (NAICS 11411) for RFA compliance purposes. NMFS considers all HMS permit holders to be small entities because they had average annual receipts of less than \$11 million for commercial fishing. The SBA has established size standards for all other major industry sectors in the U.S., including the scenic and sightseeing transportation (water) sector (NAICS code 487210, for-hire), which includes charter/party boat entities. The SBA has defined a small charter/party boat entity as one with average annual receipts (revenue) of less than \$7.5 million.

Regarding those entities that would be directly affected by the recreational management measures, HMS Angling (Recreational) category permits are typically obtained by individuals who are not considered businesses or small entities for purposes of the RFA because they are not engaged in commercial business activity. Vessels with the HMS Charter/Headboat category permit can operate as for-hire vessels. These permit holders can be regarded as small entities for RFA purposes (*i.e.*, they are engaged

in the business of fish harvesting, are independently owned or operated, are not dominant in their field of operation, and have average annual revenues of less than \$7.5 million). Overall, the recreational alternatives would have impacts on the portion of the 3,618 HMS Charter/Headboat permit holders who fish for or retain sharks. There were also 282 registered HMS tournaments in 2017, which could be impacted by this rule. Of those registered HMS tournaments, 72 had awards or prizes for pelagic sharks.

Regarding those entities that would be directly affected by the preferred commercial alternatives, the average annual revenue per active pelagic longline vessel is estimated to be \$187,000 based on the 170 active vessels between 2006 and 2012 that produced an estimated \$31.8 million in revenue annually. The maximum annual revenue for any pelagic longline vessel between 2006 and 2016 was less than \$1.9 million, well below the NMFS small business size standard for commercial fishing businesses of \$11 million. Other non-longline HMS commercial fishing vessels typically generally earn less revenue than pelagic longline vessels. Therefore, NMFS considers all Atlantic HMS commercial permit holders to be small entities (*i.e.*, they are engaged in the business of fish harvesting, are independently owned or operated, are not dominant in their field of operation, and have combined annual receipts not in excess of \$11 million for all its affiliated operations worldwide). The preferred commercial alternatives would apply to the 280 Atlantic tunas Longline category permit holders, 221 directed shark permit holders, and 269 incidental shark permit holders. Of these 280 permit holders, 85 pelagic longline vessels were actively fishing in 2016 based on logbook records. Based on HMS logbook data, an average of 10 vessels that used gear other than pelagic longline gear interacted with shortfin mako sharks between 2012 and 2016, which is also equal to the 2016 number of vessels reporting shortfin mako sharks on non-pelagic longline gear.

NMFS has determined that the preferred alternatives would not likely directly affect any small organizations or small government jurisdictions defined under RFA, nor would there be disproportionate economic impacts between large and small entities. Furthermore, there would be no disproportionate economic impacts among the universe of vessels based on gear, home port, or vessel length. More information regarding the description of the fisheries affected, and the categories

and number of permit holders, can be found in Chapter 3 of the DEIS.

Section 603(b)(4) of the RFA requires Agencies to describe any new reporting, record-keeping and other compliance requirements. The action does not contain any new collection of information, reporting, or record-keeping requirements.

Under section 603(b)(5) of the RFA, Agencies must identify, to the extent practicable, relevant Federal rules which duplicate, overlap, or conflict with the proposed action. Fishermen, dealers, and managers in these fisheries must comply with a number of international agreements, domestic laws, and other fishery management measures. These include, but are not limited to, the Magnuson-Stevens Act, ATCA, the High Seas Fishing Compliance Act, the Marine Mammal Protection Act, the Endangered Species Act, the National Environmental Policy Act, the Paperwork Reduction Act, and the Coastal Zone Management Act. This proposed action has been determined not to duplicate, overlap, or conflict with any Federal rules.

One of the requirements of an IRFA is to describe any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. The analysis shall discuss significant alternatives such as:

1. Establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
2. Clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
3. Use of performance rather than design standards; and
4. Exemptions from coverage of the rule, or any part thereof, for small entities.

These categories of alternatives are described at 5 U.S.C. 603(c)(1)–(4)). NMFS examined each of these categories of alternatives. Regarding the first, second, and fourth categories, NMFS cannot establish differing compliance or reporting requirements for small entities or exempt small entities from coverage of the rule or parts of it because all of the businesses impacted by this rule are considered small entities and thus the requirements are already designed for small entities. NMFS does not know of any performance or design standards that would satisfy the aforementioned objectives of this rulemaking while, concurrently, complying with the

Magnuson-Stevens Act. As described below, NMFS analyzed several different alternatives from different categories in this proposed rulemaking and provides rationales for identifying the preferred alternatives to achieve the desired objectives.

The alternatives considered and analyzed are described below. The IRFA assumes that each vessel will have similar catch and gross revenues to show the relative impact of the proposed action on vessels.

Commercial Alternatives

Alternative A1, the No Action alternative, would keep the non-emergency rule regulations for shortfin mako sharks. Once the emergency rule for shortfin mako sharks expires, management measures would revert back to those effective before March 2018 (*e.g.*, no requirement to release shortfin mako sharks that are alive at haulback). Directed and incidental shark LAP holders would continue to be allowed to land and sell shortfin mako sharks to an authorized dealer, subject to current limits, including the pelagic shark commercial quota. Short-term direct economic impacts on small entities would likely be neutral since commercial fishermen could continue to catch and retain shortfin mako sharks at a similar level and rate as the status quo.

In recent years, about 180,000 lb dressed weight (dw) of shortfin mako sharks have been landed and the commercial revenues from shortfin mako sharks have averaged approximately \$375,000 per year, which equates to approximately 1 percent of overall HMS ex-vessel revenues. Approximately 97.26 percent of shortfin mako commercial landings, based on dealer reports, were made by pelagic longline vessels. There were 85 pelagic longline vessels that were active in 2016 based on logbook reports. Therefore, the average revenue from shortfin mako shark landings per pelagic longline vessel is \$4,291 per year.

Even though pelagic longline gear is the primary commercial gear used to land shortfin mako sharks, other gear types also occasionally interact with this species. Based on HMS logbook data, an average of 10 vessels that used gear other than pelagic longline gear interacted with shortfin mako sharks between 2012 and 2016, which is also equal to the 2016 number of vessels reporting shortfin mako sharks on non-pelagic longline gear. Therefore, these vessels that used gear other than pelagic longline gear landed an average of only \$1,028 worth of shortfin mako sharks per year.

Under Alternative A2, the preferred alternative, retention of shortfin mako sharks would only be allowed if the following three criteria are met: (1) The vessel has been issued a Directed or Incidental shark LAP, (2) the shark is dead at haulback, and (3) there is a functional electronic monitoring system on board the vessel. This alternative is designed to be consistent with one of the limited provisions allowing retention of shortfin mako sharks under ICCAT Recommendation 17–08. Under the current HMS regulations, all HMS permitted vessels that fish with pelagic longline gear are already required to have a functional electronic monitoring system (79 FR 71510; December 2, 2014) and either a Directed or an Incidental shark LAP. Vessels utilizing other gear types (*i.e.*, gillnet or bottom longline) are not required to have an electronic monitoring system under current regulations but could choose to install one if the operator wishes to retain shortfin mako sharks that are dead at haulback and if the vessel holds a commercial shark LAP. Under this alternative, the electronic monitoring system would be used to verify the disposition of shortfin mako sharks at haulback to ensure that only sharks dead at haulback were retained.

This alternative would be consistent with ICCAT Recommendation 17–08 and would reduce the number of landings by pelagic longline vessels on average by 74 percent based on observer data from 2013–2016. A 74 percent reduction in shortfin mako landings would reduce revenues by an average of \$3,175 per vessel for the 85 active pelagic longline vessels and would eliminate all of the \$1,028 in landing per vessel by the 10 non-pelagic longline vessels that landing shortfin mako sharks since those vessels are unlikely to have electronic monitoring systems currently installed. Those non-pelagic longline vessels would need to pay to install electronic monitoring systems if they wish to retain shortfin mako sharks, introducing an additional expense for those vessels if it there were an economic incentive for those vessels to try to retain shortfin mako sharks under this alternative. Overall, this alternative would have minor economic costs on small entities because these measures would reduce the number of shortfin mako sharks landed and sold by these fishing vessels. However, shortfin mako sharks are rarely a target species and are worth less than other more valuable target species.

Alternative A3 is similar to Alternative A2 except that the ability to retain dead shortfin mako sharks would be limited to permit holders that opt in

to a program that would use the existing electronic monitoring systems, which are currently used in relation to the bluefin tuna IBQ program, also to verify the disposition of shortfin mako sharks at haulback. In other words, this alternative would allow for retention of shortfin mako sharks that are dead at haulback by persons with a Directed or Incidental shark LAP only if permit holders opt in to enhanced electronic monitoring coverage. If the permit holder does not opt in to the enhanced electronic monitoring coverage, they could not retain any shortfin mako sharks.

The economic impacts to small entities under this alternative are expected to be similar to those under Alternative A2. Under this alternative, a portion of the pelagic longline fleet could opt out of any retention of shortfin mako sharks, resulting in a greater reduction in overall shark ex-vessel revenue for those vessels. Overall, the socioeconomic impacts associated with these reductions in revenue are not expected be substantial, as shortfin mako sharks comprise less than one percent of total HMS ex-vessel revenues on average. Non-pelagic longline vessels would need to pay to install electronic monitoring systems if they wish to retain shortfin mako sharks, introducing an additional expense for those vessels. Due to the low commercial value of shortfin mako sharks and the high cost of electronic monitoring it is reasonable to expect that these fisheries will not install cameras and therefore will not retain shortfin mako sharks. Overall, this alternative would have minor economic costs on small entities, because these measures would reduce the number of shortfin mako sharks landed and sold by these fishing vessels, however, shortfin mako sharks are rarely a target species and are worth less than other more valuable target species.

Alternative A4 would establish a commercial minimum size of 83 inches FL (210 cm FL) for retention of shortfin mako sharks caught incidentally during fishing for other species, whether the shark is dead or alive at haulback. Based on observer data, only six percent of shortfin mako sharks caught with pelagic longline gear greater than 83 inches FL. Thus, restricting fishermen to retaining six percent of shortfin mako sharks would represent a considerable reduction in number of shortfin mako sharks landed and in the resulting ex-vessel revenue. A 94 percent reduction in shortfin mako landings would reduce annual revenues by an average of \$4,034 per vessel for the 85 active pelagic longline vessels and would reduce

annual revenues by an average of \$966 per vessel for the 10 non-pelagic longline vessels that land shortfin mako sharks. However, the overall economic impacts associated with these reductions in revenue are not expected be substantial, as shortfin mako sharks comprise less than one percent of total HMS ex-vessel revenues on average. Additionally, the magnitude of shortfin mako landings by other gear types (*e.g.*, bottom longline, gillnet, handgear) is very small. Overall, this alternative would have minor economic costs on small entities because these measures would reduce the number of shortfin mako sharks landed and sold by these fishing vessels, however, shortfin mako sharks are rarely a target species and are worth less than other more valuable target species.

Alternative A5 would allow fishermen to retain shortfin mako sharks caught on any commercial gear (*e.g.*, pelagic longline, bottom longline, gillnet, handgear) provided that an observer is on board that can verify that the shark was dead at haulback. Under this alternative, electronic monitoring would not be used to verify the disposition of shortfin mako sharks caught on pelagic longline gear, but instead pelagic longline vessels could only retain shortfin mako sharks when the sharks are dead at haulback and an observer is on board.

Since only 5 percent of pelagic longline gear trips are observed, this alternative would result in a 95 percent reduction in the number of shortfin mako sharks retained on pelagic longline gear. A 95 percent reduction in shortfin mako landings would reduce annual revenues by an average of \$4,076 per vessel for the 85 active pelagic longline vessels and would reduce annual revenues by an average of \$977 per vessel for the 10 non-pelagic longline vessels that land shortfin mako sharks. However, the overall economic impacts associated with these reductions in revenue are not expected be substantial, as shortfin mako sharks comprise less than one percent of total HMS ex-vessel revenues on average. Additionally, the magnitude of shortfin mako landings by other gear types (*e.g.*, bottom longline, gillnet, handgear) is very small. Overall, this alternative would have minor economic costs on small entities because these measures would reduce the number of shortfin mako sharks landed and sold by these fishing vessels, however, shortfin mako sharks are rarely a target species and are worth less than other more valuable target species.

Alternative A6 would place shortfin mako sharks on the prohibited sharks

list to prohibit any catch or retention of shortfin mako sharks in commercial HMS fisheries. In recent years, about 180,000 lb dw of shortfin mako sharks have been landed and the commercial revenues from shortfin mako sharks have averaged approximately \$375,000 per year, which equates to approximately one percent of overall HMS ex-vessel revenues. That revenue would be eliminated under this alternative. Approximately 97.26 percent of shortfin mako commercial landings, based on dealer reports, were made by pelagic longline vessels. There were 85 pelagic longline vessels that were active in 2016 based on logbook reports. Therefore, the average loss in annual revenue from shortfin mako shark landings per pelagic longline vessel would be \$4,291 per year. The average loss in annual revenue from shortfin mako shark landings for vessel using other gear types would be \$1,028 per year. However, the overall economic impacts associated with these reductions in revenue are not expected to be substantial, as shortfin mako sharks comprise less than one percent of total HMS ex-vessel revenues on average. Additionally, the magnitude of shortfin mako landings by other gear types (e.g., bottom longline, gillnet, handgear) is very small. Overall, this alternative would have minor economic costs on small entities because these measures would reduce the number of shortfin mako sharks landed and sold by these fishing vessels, however, shortfin mako sharks are rarely a target species and are worth less than other more valuable target species.

Recreational Alternatives

While HMS Angling permit holders are not considered small entities by NMFS for purposes of the Regulatory Flexibility Act, Charter/Headboat permit holders and tournament operators are considered to be small entities and could be potentially impacted by the various recreational alternatives, as described below.

Alternative B1, the no action alternative, would not implement any management measures in the recreational shark fishery to decrease mortality of shortfin mako sharks. This would result in no additional economic impacts on small entities associated with this fishery in the short-term.

Under Alternative B2, the minimum size limit for the retention of shortfin mako sharks would be increased from 54 inches FL to 71 inches FL for male and 83 inches FL for female shortfin mako sharks. This increase in the size limit is projected to reduce recreational landings by at least 64 percent in

numbers of sharks landed, and 49 percent in the weight of sharks landed. While this alternative would not establish a shortfin mako fishing season, such a significant increase in the minimum size limit would likely result in some reduction in directed fishing effort for shortfin mako sharks.

Under Alternative B3, the preferred alternative, the minimum size limit for retention of shortfin mako sharks would be increased to 83 inches FL for both males and female sharks consistent with the measure implemented in the emergency rule. Assuming no reduction in directed fishing effort, this increase in the minimum size limit would result in an 83 percent reduction in the number of sharks landed, and a 68 percent reduction in the weight of sharks landed. Such a large increase in the minimum size limit and associated reduction in landings is unlikely to have no effect on directed fishing effort. An 83 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them to 6 percent. At least one tournament directed at shortfin mako sharks in the Northeast has chosen to cancel its 2018 event due to the more stringent current 83 inches FL minimum size limit. Tournaments account for over half of directed recreational trips for shortfin mako sharks, and 77 percent of them in the month of June when effort is at its highest. This could result in a significant reduction in directed fishing trips for shortfin mako sharks, thus leading to moderate adverse economic impacts on some charter/headboats and tournament operators.

Under Alternative B4, recreational HMS permit holders would only be allowed to retain male shortfin mako sharks that measure at least 71 inches FL and female shortfin mako sharks that measure at least 108 inches FL. Assuming no reduction in directed fishing effort, this increase in the minimum size limit would result in a 76 percent reduction in the number of sharks landed, and a 72 percent reduction in the weight of sharks landed. A 76 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them to approximately 9 percent. This could result in a significant reduction in directed fishing trips for shortfin mako sharks, thus leading to moderate adverse economic impacts on some charter/headboats and tournament operators.

Under Alternative B5, recreational HMS permit holders would only be allowed to retain male shortfin mako sharks that measure at least 71 inches FL and female shortfin mako sharks that

measure at least 120 inches FL. Assuming no reduction in directed fishing effort, this increase in the size limit would result in a 76 percent reduction in the number of sharks landed, and a 73 percent reduction in the weight of sharks landed. A 76 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them to 8.6 percent. This could result in a significant reduction in directed fishing trips for shortfin mako sharks, thus leading to moderate adverse economic impacts on some charter/headboats and tournament operators.

Under Alternative B6a, the minimum size limit for the retention of shortfin mako sharks would be increased from 54 inches FL to 71 inches FL for male and 83 inches FL for female shortfin mako sharks, and a shortfin mako fishing season would be established from May through October. The fishing season established under this alternative would have little to no effect on shortfin mako fishing activity in the Northeast, but may reduce fishing effort in the South Atlantic and Gulf of Mexico regions; however, a lack of data on targeted trips for shortfin mako sharks in this region makes any assessment of potential socioeconomic impacts difficult. However, this combination of increase in the size limit and fishing season is projected to reduce recreational landings by at least 64 percent in numbers of sharks landed, and 49 percent in the weight of sharks landed in the Northeast. A 64 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them to 13 percent. This reduction on directed trips could lead to moderate adverse economic impacts on some charter/headboats and tournament operators.

Under Alternative B6b, NMFS would establish a three-month fishing season for shortfin mako sharks spanning the summer months of June through August. This season would be combined with a 71 inches FL minimum size limit for males and 100 inches FL for females. Based on estimates from the Large Pelagics Survey, on average 475 directed trips are taken for shortfin mako sharks each September and October, representing approximately 10 percent of all annual directed trips. No registered HMS tournaments held in September and October target sharks exclusively, so it is highly unlikely this alternative would result in the rescheduling of any tournaments due to the fishing season. It is much more likely that directed fishing effort would be affected by the increases in the

minimum size limits. Assuming this increase in the size limit has minimal effect on fishing effort directly towards shortfin mako sharks within the season, this combination of season and increase in the size limit should result in a 78 percent reduction in the number of sharks landed, and a 76 percent reduction in the weight of sharks landed. This reduction could result in a significant reduction in directed fishing trips for shortfin mako sharks, thus leading to moderate adverse economic impacts on some charter/headboat operators.

Under Alternative B6c, NMFS would establish a two-month fishing season for shortfin mako sharks for the months of June and July. This season would be combined with a 71 inches FL minimum size limit for males and 90 inches FL for females. Based on estimates from the Large Pelagics Survey, on average 1,264 directed trips are taken for shortfin mako sharks each August through October, representing approximately 26 percent of all annual directed trips. Only two registered HMS tournaments held in August through October target sharks exclusively, one out of New York that primarily targets thresher sharks and one out of Florida where participants fish exclusively from shore. Thus, it is highly unlikely this alternative would result in the rescheduling of any tournaments due to the fishing season. It is likely that directed fishing effort would also be affected by the increases in the minimum size limits. Assuming this increase in the size limit has minimal effect on fishing effort directly towards shortfin mako sharks within the season, this combination of season and increase in the size limit should result in a 78 percent reduction in the number of sharks landed, and a 76 percent reduction in the weight of sharks landed. Such a large increase in the size limit and associated reduction in landings is unlikely to have no effect on directed fishing effort. A 78 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them to 8 percent. This reduction in directed trips could lead to moderate adverse economic impacts on some charter/headboats and tournament operators.

Under Alternative B6d, NMFS would establish a one-month fishing season for shortfin mako sharks for the month of June only. This season would be combined with a 71 inches FL minimum size limit for males and 83 inches FL for females. Based on estimates from the Large Pelagics Survey, on average 2,435 directed trips

are taken for shortfin mako sharks each July through October, representing approximately 51 percent of all annual directed trips. Additionally, there are seven registered HMS tournaments held in July through October that target sharks exclusively, including three of four tournaments held in the state of Rhode Island, and the only tournament in Massachusetts to target sharks exclusively. It is likely that directed fishing effort would also be affected by the increases in the minimum size limits. Assuming this increase in the size limit has minimal effect on fishing effort directly towards shortfin mako sharks within the season, this combination of season and increase in the size limit should result in a 79 percent reduction in the number of sharks landed, and a 78 percent reduction in the weight of sharks landed. Such a large increase in the size limit and associated reduction in landings is unlikely to have no effect on directed fishing effort. A 79 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them to 8 percent. This reduction in directed trips could lead to moderate adverse economic impacts on some charter/headboats and tournament operators.

Under Alternative B6e, NMFS would establish a process and criteria for determining season dates and minimum size limits for shortfin mako sharks on an annual basis through inseason actions. This process would be similar to how the agency sets season opens and retention limits for the shark commercial fisheries and the Atlantic Tunas General category fishery. NMFS would review data on recreational landings, catch rates, and effort levels for shortfin mako sharks in the previous years, and establish season dates and minimum size limits that would be expected to achieve the reduction targets established by ICCAT, and the objectives of the HMS fisheries management plan. This alternative would also allow NMFS to minimize adverse economic impacts to the HMS recreational fishery by allowing for adjustments to the season and size limits based on observed reductions and redistribution of fishing effort resulting from measures implemented in previous years.

Under Alternative B7, NMFS would implement a "slot limit" for shortfin mako sharks in the recreational fishery. Under a slot limit, recreational fishermen would only be allowed to retain shortfin mako sharks within a narrow size range (e.g., between 71 and 83 inches FL) with no retention above

or below that slot. Assuming no reduction in directed fishing effort, this alternative would be expected to result in similar reductions in landings as other alternatives analyzed here. While this alternative would not establish a shortfin mako fishing season, as described above in earlier alternatives, such a significant increase in the size limit would likely result in some reduction in directed fishing effort for shortfin mako sharks. This reduction in effort may be further exacerbated by the complicated nature of slot limits regulations. Similar to Alternative B2, there are two factors that might minimize reductions in fishing effort (harvested shortfin mako sharks peaks between 71 and 77 inches FL and shifting focus to other HMS species). The amount of effort reduction by recreational fishermen would depend on how much HMS anglers and tournaments are satisfied to practice catch-and-release fishing for sub-legal shortfin mako sharks or shift their fishing effort to other species.

Under Alternative B8, NMFS would establish a landings tag requirement and a yearly limit on the number of landings tags assigned to a vessel, for shortfin mako sharks over the minimum size limit. This requirement would be expected to negatively affect fishing effort. An increase in the minimum size limit and a yearly cap on landings for vessels would reduce effort drastically, while maintaining some opportunity for the recreational fleet. This effort reduction would adversely affect the charter fleet the most by limiting the number of trips that they could land shortfin mako sharks each year. This effort reduction may also affect their ability to book trips. At least one tournament directed at shortfin mako sharks in the Northeast has chosen to cancel its 2018 event due to the more stringent current 83 inches FL minimum size limit. By excluding tournaments from a landings tag requirement there may be a direct beneficial economic impact for tournaments, as this would be an additional opportunity, beyond their tags, to land shortfin mako sharks for permit holders.

Alternative B9, a preferred alternative, would expand the requirement to use non-offset, non-stainless steel circle hook by all HMS permit holders with a shark endorsement when fishing for sharks recreationally, except when fishing with flies or artificial lures, to all waters managed within HMS management division. Currently, this requirement is in place for all Federally managed waters south of 41°43' N latitude (near Chatham, Massachusetts), but this alternative would remove the

boundary line, requiring fishermen in all areas to use circle hooks. Recreational shark fishermen north of Chatham, Massachusetts would need to purchase circle hooks to comply with this requirement, although the cost is modest. Additionally, it is possible that once the circle hook requirement is expanded, fishermen in the newly impacted area could find reduced catch rates of sharks including shortfin mako sharks. If reduced catch rates are realized, effort in the recreational shark fishery, including the for-hire fleet, could be impacted by reduced number of trips or reduced demand for chartered trips.

Alternative B10 would place shortfin mako sharks on the prohibited sharks list to prohibit the retention of shortfin mako sharks in recreational HMS fisheries. HMS permit holders would be prohibited from retaining or landing shortfin mako sharks recreationally. In recreational fisheries, recreational fishermen would only be authorized to catch and release shortfin mako sharks. A prohibition on the retention of shortfin mako sharks is likely to disincentivize some portion of the recreational shark fishery, particularly those individuals that plan to target shortfin mako sharks. Businesses that rely on recreational shark fishing such as tournament operators and charter/headboats may experience a decline in demand resulting in adverse economic impacts.

Monitoring Alternatives

Alternative C1, the preferred alternative, would make no changes to the current reporting requirements applicable to shortfin mako sharks in HMS fisheries. Since there would be no changes to the reporting requirements under this alternative, NMFS would expect fishing practices to remain the same and direct economic impacts in small entities to be neutral in the short-term.

Under Alternative C2, NMFS would require vessels with a directed or incidental shark LAP to report daily the number of shortfin mako sharks retained and discarded dead, as well as fishing effort (number of sets and number of hooks) on a vessel monitoring system (VMS). A requirement to report shortfin mako shark catches on VMS for vessels with a shark LAP would be an additional reporting requirement for those vessels on their existing systems. For other commercial vessels that are currently only required to report in the HMS logbook, the requirement would mean installing VMS to report dead discards of shortfin mako and fishing effort.

If a vessel has already installed a type-approved enhanced mobile transmitting unit (E-MTU) VMS unit, the only expense would be monthly communication service fees, which they may already be paying if the vessel is participating in a Council-managed fishery. Existing regulations require all vessel operators with E-MTU VMS units to provide hail out/in declarations and provide location reports on an hourly basis at all times while they are away from port. In order to comply with these regulations, vessel owners must subscribe to a communication service plan that includes an allowance for sending similar declarations (hail out/in) describing target species, fishing gear possessed, and estimated time/location of landing using their E-MTU VMS. Given that most shortfin mako sharks are incidentally caught by pelagic longline vessels that are already required to have an E-MTU VMS system onboard, adverse economic impacts are not expected. If vessels with a shark LAP do not have an E-MTU VMS unit, direct, economic costs are expected as a result of having to pay for the E-MTU VMS unit (approximately \$4,000) and a qualified marine electrician to install the unit (\$400). VMS reporting requirements under this alternative could potentially provide undue burden to HMS commercial vessels that already report on catches, landings, and discards through vessel logbooks, dealer reports, and observer reports.

Alternative C3 would implement mandatory reporting of all recreational interactions (landed and discarded) of shortfin mako sharks in HMS fisheries. Recreational HMS permit holders would have a variety of options for reporting shortfin mako shark landings including a phone-in system, internet website, and/or a smartphone app. HMS Angling and Charter/Headboat permit holders currently use this method for required reporting of each individual landing of bluefin tuna, billfish, and swordfish within 24 hours. NMFS has also maintained a shortfin mako shark reporting app as an educational tool to encourage the practice of catch-and-release. Additionally, the potential burden associated with mandatory landings reports for shortfin mako sharks would be significantly reduced under the increased minimum size limits being considered in this rulemaking, although it would still represent an increased burden over current reporting requirements. While HMS Angling permit holders are not considered small entities by NMFS for purposes of the Regulatory Flexibility

Act, Charter/Headboat permit holders are considered to be small entities and would be potentially impacted by this alternative.

Rebuilding Alternatives

Under Alternative D1, NMFS would not establish a rebuilding plan for shortfin mako sharks and would maintain the current recreational and commercial shark fishing regulations that pertain to shortfin mako sharks in U.S. fisheries. There would likely be no direct short-term impact on small entities from this alternative as there would be no change in fishing effort or landings of shortfin mako sharks that would impact revenues generated from the commercial and recreational fisheries.

Under Alternative D2, NMFS would establish a domestic rebuilding plan for shortfin mako sharks unilaterally (*i.e.*, without ICCAT). While such an alternative could avoid overfishing shortfin mako sharks in the United States by changing the way that the U.S. recreational and commercial fisheries operate, such a plan could not effectively rebuild the stock, since U.S. catches are only 11 percent of the reported catch Atlantic-wide. Such an alternative would be expected to cause short- and long-term direct economic impacts.

Under Alternative D3, the preferred alternative, NMFS would take preliminary action toward rebuilding by adopting measures to end overfishing to establish a foundation for a rebuilding plan. NMFS would then take action at the international level through ICCAT to develop a rebuilding plan for shortfin mako sharks. ICCAT is planning to establish a rebuilding plan for shortfin mako sharks in 2019, and this rebuilding plan would encompass the objectives set forth by ICCAT based on scientific advice from the SCRS. This alternative would not result in any changes to the current recreational and commercial domestic regulations for shortfin mako sharks in the short-term. There would likely be no direct short-term impact on small entities from this alternative as there would be no change in fishing effort or landings of shortfin mako sharks that would impact revenues generated from the commercial and recreational fisheries. Management measures to address overfishing of shortfin mako sharks could be adopted in 2019. These measures could change the way that the U.S. recreational and commercial shortfin mako shark fishery operates, which could cause long-term direct economic impacts. Any future action to implement international

measures would be analyzed in a separate rulemaking.

Under Alternative D4, NMFS would remove shortfin mako sharks from the commercial pelagic shark management group and would implement a species-specific quota for shortfin mako sharks as established by ICCAT, which would include both commercial and recreational catches as well as dead discards. In addition, NMFS would establish a new commercial pelagic shark species quota for common thresher and oceanic whitetip sharks based on recent landings. The 2017 ICCAT stock assessment indicated that the North Atlantic population of shortfin mako sharks is overfished and experiencing overfishing. In November 2017, ICCAT adopted management measures (Recommendation 17–08) to address the overfishing determination, but did not recommend a total allowable catch (TAC) necessary to stop overfishing of shortfin mako sharks. Therefore, it is difficult at this time to determine how setting a species-specific quota for shortfin mako sharks would affect commercial and recreational fishing operations. However, this species-specific quota may provide long-term direct, minor adverse economic impacts if ICCAT established a TAC for the United States that is well below the total average harvest by the United States (*i.e.*, 379 mt whole weight (ww) or 195 mt dw) or below the current annual commercial quota for common thresher, oceanic whitetip, and shortfin mako (488 mt dw) as it could potentially limit the amount of harvest for fishermen. Short-term direct socioeconomic impacts would be neutral for Alternative D4 because initially there would be no reduction in fishing effort and practices.

Under Alternative D5, NMFS would take steps to implement area-based management measures domestically if such measures are established by ICCAT. Recommendation 17–08 calls on the SCRS to provide additional scientific advice in 2019 that takes into account a spatial/temporal analysis of North Atlantic shortfin mako shark catches in order to identify areas with high interactions. Without a specific area to analyze at this time, the precise impacts with regard to impacts on commercial and recreational fishery operations cannot be determined. Implementing area management for shortfin mako sharks, if recommended by the scientific advice, could lead to a reduction in localized fishing effort, which would likely have adverse economic impacts for small entities that land shortfin mako sharks.

Under Alternative D6, NMFS would establish bycatch caps for fisheries that interact with shortfin mako sharks. This alternative would impact the HMS pelagic longline and shark recreational fisheries similar to Alternative D4. However, this alternative could also impact non-HMS fisheries by closing those fisheries if the bycatch cap were reached. This alternative could lead to short-term adverse impacts since the bycatch caps could close fisheries if they are reached until those fishermen could modify fishing behavior to avoid shortfin mako sharks (even in fisheries where shortfin mako sharks are rarely, if ever, seen) and reduce interactions. In the long-term, this alternative would have neutral impacts as the vessels would avoid shortfin mako sharks. The impacts to small businesses are expected to be neutral in the short and long-term as their businesses would not change.

List of Subjects in 50 CFR Part 635

Fisheries, Fishing, Fishing vessels, Foreign relations, Imports, Penalties, Reporting and recordkeeping requirements, Treaties.

Dated: July 19, 2018.

Samuel D. Rauch, III,
Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 635 is proposed to be amended as follows:

PART 635—ATLANTIC HIGHLY MIGRATORY SPECIES

■ 1. The authority citation for part 635 continues to read as follows:

Authority: 16 U.S.C. 971 *et seq.*; 16 U.S.C. 1801 *et seq.*

■ 2. Revise definition for “FL (fork length)” to read as follows:

§ 635.2 Definitions.

* * * * *

FL (fork length) means the straight-line measurement of a fish from the midpoint of the anterior edge of the fish to the fork of the caudal fin. The measurement is not made along the curve of the body.

* * * * *

■ 3. In § 635.20, remove paragraph (e)(7), lift the suspension on paragraphs (e)(2) and (e)(6), and revise paragraphs (e)(2) and (e)(6) to read as follows:

§ 635.20 Size limits.

* * * * *

(e) * * *

(2) All sharks, except as otherwise specified in paragraphs (e)(1) through

(e)(6) of this section, landed under the recreational retention limits specified at § 635.22(c)(2) must be at least 54 inches (137 cm) FL.

* * * * *

(6) All North Atlantic shortfin mako sharks landed under the recreational retention limits specified at § 635.22(c)(2) must be at least 83 inches (210 cm) fork length.

* * * * *

■ 4. In § 635.21, revise paragraphs (a)(4), (c)(1)(iv), (f)(2) and (3), and (k)(1) and (2) to read as follows:

§ 635.21 Gear operation and deployment restrictions.

(a) * * *

(4) Any person on board a vessel that is issued a commercial shark permit must release all shortfin mako sharks, whether alive or dead, caught with any gear other than pelagic longline gear.

* * * * *

(c) * * *

(1) * * *

(iv) Has pelagic longline gear on board, persons aboard that vessel are required to promptly release in a manner that causes the least harm any shortfin mako shark that is alive at the time of haulback. Any shortfin mako shark that is dead at the time of haulback may be retained provided the electronic monitoring system is installed and functioning in compliance with the requirements at § 635.9.

* * * * *

(f) * * *

(2) A person on board a vessel that has been issued or is required to be issued a permit with a shark endorsement under this part and who is participating in an HMS registered tournament that bestows points, prizes, or awards for Atlantic sharks must deploy only non-offset, corrodible circle hooks when fishing for, retaining, possessing, or landing sharks, except when fishing with flies or artificial lures.

(3) A person on board a vessel that has been issued or is required to be issued an HMS Angling permit with a shark endorsement or an HMS Charter/Headboat permit with a shark endorsement must deploy only non-offset, corrodible circle hooks when fishing for, retaining, possessing, or landing sharks, except when fishing with flies or artificial lures.

* * * * *

(k) * * *

(1) A person on board a vessel that has been issued or is required to be issued a permit with a shark endorsement under this part and who is participating in an HMS registered

tournament that bestows points, prizes, or awards for Atlantic sharks must deploy only non-offset, corrodible circle hooks when fishing for, retaining, possessing, or landing sharks, except when fishing with flies or artificial lures.

(2) A person on board a vessel that has been issued or is required to be issued an HMS Angling permit with a shark endorsement or a person on board a vessel with an HMS Charter/Headboat permit with a shark endorsement must deploy only non-offset, corrodible circle hooks when fishing for, retaining, possessing, or landing, except when fishing with flies or artificial lures.

* * * * *

■ 5. In § 635.24, remove paragraphs (a)(4)(v) and (vi), lift the suspension for paragraphs (a)(4)(i) and (iii), and revise paragraphs (a)(4)(i) and (iii) to read as follows:

§ 635.24 Commercial retention limits for sharks, swordfish, and BAYS tunas.

* * * * *

(a) * * *

(4) * * *

(i) A person who owns or operates a vessel that has been issued a directed shark LAP may retain, possess, or land pelagic sharks if the pelagic shark fishery is open per §§ 635.27 and 635.28. Shortfin mako sharks may only be retained by persons using pelagic longline gear, and only if each shark is dead at the time of haulback per § 635.21 (c)(1).

* * * * *

(iii) Consistent with paragraph (a)(4)(ii) of this section, a person who owns or operates a vessel that has been issued an incidental shark LAP may retain, possess, land, or sell no more than 16 SCS and pelagic sharks, combined, per vessel per trip, if the respective fishery is open per §§ 635.27 and 635.28. Of those 16 SCS and pelagic sharks per vessel per trip, no more than 8 shall be blacknose sharks. Shortfin mako sharks may only be retained by persons using pelagic longline gear, and only if each shark is dead at the time of haulback per § 635.21(c)(1).

* * * * *

■ 6. In § 635.30, paragraph (c)(4) is revised to read as follows:

§ 635.30 Possession at sea and landing.

* * * * *

(c) * * *

(4) Persons aboard a vessel that has been issued or is required to be issued a permit with a shark endorsement must maintain a shark intact through landing and offloading with the head, tail, and all fins naturally attached. The shark

may be bled and the viscera may be removed.

* * * * *

■ 7. In § 635.71, revise paragraphs (d)(22), (23), (27), (28), and (29) to read as follows:

§ 635.71 Prohibitions.

* * * * *

(d) * * *

(22) Except when fishing only with flies or artificial lures, fish for, retain, possess, or land sharks without deploying non-offset, corrodible circle hooks when fishing at a registered recreational HMS fishing tournament that has awards or prizes for sharks, as specified in § 635.21(f) and (k).

(23) Except when fishing only with flies or artificial lures, fish for, retain, possess, or land sharks without deploying non-offset, corrodible circle hooks when issued an Atlantic HMS Angling permit or HMS Charter/Headboat permit with a shark endorsement, as specified in § 635.21(f) and (k).

* * * * *

(27) Retain, land, or possess a shortfin mako shark that was caught with gear other than pelagic longline gear as specified at § 635.21(a).

(28) Retain, land, or possess a shortfin mako shark that was caught with pelagic longline gear and was alive at haulback as specified at § 635.21(c)(1).

(29) As specified at § 635.21(c)(1), retain, land, or possess a shortfin mako shark that was caught with pelagic longline gear when the electronic monitoring system was not installed and functioning in compliance with the requirements at § 635.9.

* * * * *

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

RIN 0648–BH16

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Amendment 20 to the Atlantic Mackerel, Squid, and Butterfish Fishery Management Plan

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

ACTION: Announcement of availability of fishery management plan amendment; request for comments.

SUMMARY: NMFS announces that the Mid-Atlantic Fishery Management Council has submitted Amendment 20 to the Atlantic Mackerel, Squid, and Butterfish Fishery Management Plan to the Secretary of Commerce for review and approval. We are requesting comments from the public on this amendment. This action is necessary to prevent the reactivation of latent effort in the longfin squid fishery, preserve economic opportunities for more recently active participants in the longfin squid fishery, avoid overharvest during Trimester II (May–August) of the longfin squid fishery, and reduce potential negative impacts on inshore spawning longfin squid aggregations and egg mops. The Mid-Atlantic Fishery Management Council intends that these proposed measures would promote the sustainable utilization and conservation of the squid and butterfish resources, while promoting the sustained participation of fishing communities and minimizing adverse economic impacts on such communities.

DATES: Comments must be received on or before September 25, 2018.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2017–0110, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to www.regulations.gov #/docketDetail;D=NOAA-NMFS-2017-0110, click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

- *Mail:* Michael Pentony, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, “Comments on Amendment 20.”

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

The Council prepared an environmental assessment (EA) for Amendment 20 to the Atlantic Mackerel, Squid, and Butterfish Fishery Management Plan (FMP) that describes the proposed action and other alternatives considered and provides a thorough analysis of the impacts of the proposed measures and alternatives considered. Copies of Amendment 20, including the EA, the Regulatory Impact Review, and the Regulatory Flexibility Act analysis, are available from: Christopher Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 State Street, Dover, DE 19901. The EA and associated analysis is accessible via the internet at: <http://www.mafmc.org/s/Squid-Amendment-Draft-EA.pdf>.

FOR FURTHER INFORMATION CONTACT:

Douglas Christel, Fishery Policy Analyst, (978) 281-9141.

SUPPLEMENTARY INFORMATION:

Background

In 1995, the Mid-Atlantic Fishery Management Council (Council) adopted a limited access permit system for longfin squid and butterfish as part of Amendment 5 to the Atlantic Mackerel, Squid, and Butterfish FMP (April 2, 1996; 61 FR 14465). Under Amendment 5, NMFS issued longfin squid/butterfish moratorium permits to vessels that landed a minimum amount of either species during a specified qualification period. Since then, the number of vessels landing longfin squid has decreased, with a relatively small portion of vessels issued longfin squid/butterfish moratorium permits landing the majority of longfin squid in recent years. The Council is concerned that unused longfin squid/butterfish moratorium permits could be activated, which could lead to excessive fishing effort and bycatch of both longfin squid and non-target species. This could cause negative biological impacts to these species. In addition, this increased effort could increase the race to fish and reduce access to available longfin squid quota by vessels with a continuous history of landings in recent years. Therefore, the Council developed Amendment 20 to consider the appropriate number of vessels in the directed and incidental longfin squid fishery and design appropriate measures to prevent unanticipated increases in fishing effort. The proposed measures described below could help prevent a race to fish, frequent and disruptive fishery closures, and reduced fishing

opportunities for vessels that are more recently dependent upon longfin squid.

Longfin squid spawning occurs year round, but is most frequently observed inshore during the late spring through early fall. Spawning aggregations and associated egg masses (mops) that are attached to the bottom are vulnerable to bottom fishing activities during the summer months when longfin squid are easily accessible to the fishery in large concentrations. In 2007, the Council implemented reduced quotas during summer months (May through August, or Trimester II) as part of the trimester quota system (January 30, 2007; 71 FR 4211). The Council developed the trimester quota system to improve the monitoring and management of the longfin squid fishery and prevent allowable quotas from being exceeded. Once a trimester quota has been caught, possession limits are reduced to incidental levels for all longfin squid permits. The FMP currently includes a possession limit of 2,500 lb (1,134 kg) per trip for incidental permits and when the directed fishery has closed. However, this incidental limit has allowed vessels to continue to land large amounts of longfin squid even after the directed fishery is closed, which contributed to the Trimester II quota being exceeded by large amounts in several years. The Council is concerned that excessive fishing effort inshore during Trimester II could negatively impact the stock, interrupting spawning activity, increasing the mortality of squid eggs, and reducing future recruitment. Measures developed by the Council under this action are intended to reevaluate the management of longfin squid during Trimester II primarily to reduce impacts to spawning squid and egg mops.

The purpose of Amendment 20 is to optimize management measures in the squid fisheries by reducing latent (unused) effort in the longfin squid fishery and adjusting the management of the longfin squid fishery during Trimester II (May through August) to avoid overharvesting the longfin squid resource. Although the Council considered reducing the number of Illex squid moratorium permits in the fishery, the Council decided a reduction in the number of Illex moratorium permits was not appropriate at this time given low Illex landings and limited vessel participation in the fishery in recent years. Measures proposed under this action would promote the sustainable utilization and conservation

of the longfin squid and butterfish resources, while promoting the sustained participation of fishing communities and minimizing adverse economic impacts on such communities. If approved, Amendment 20 would:

1. Separate butterfish from the current longfin/butterfish moratorium permit to create a new butterfish moratorium permit and a separate longfin squid moratorium permit;

2. Reissue longfin squid moratorium permits to vessels that landed at least 10,000 lb (4,536 kg) of longfin squid in any year from 1997–2013;

3. Create a new longfin squid moratorium permit with a 5,000 lb (2,268 kg) possession limit for vessels that have not landed at least 10,000 lb (4,536 kg) of longfin squid in any year from 1997–2013;

4. Create a new longfin squid incidental moratorium permit to enable vessels to continue to land 2,500 lb (1,134 kg) of longfin squid per trip;

5. Allow individual entities issued multiple longfin squid moratorium permits a one-time opportunity to swap such permits among their vessels; and

6. Reduce the longfin squid possession limit from 2,500 lb (1,134 kg) to 250 lb (113 kg) for squid/butterfish incidental catch permits and for all longfin squid permits after the Trimester II longfin squid quota is landed.

NMFS seeks public comments on Amendment 20 and its incorporated documents through the end of the comment period specified in the **DATES** section of this notice of availability (NOA). Concurrent with NMFS's review of the amendment under the Magnuson-Stevens Act procedures, NMFS may publish a rule proposing to implement measures outlined in this amendment in the **Federal Register** for public comment. All comments received by the end of the comment period on the NOA, whether specifically directed to the NOA or the proposed rule, will be considered in the approval/disapproval decision. NMFS will not consider comments received after the end of the comment period for the NOA in the approval/disapproval decision of this action.

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

Dated: July 23, 2018.

Jennifer M. Wallace,

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

[FR Doc. 2018–15970 Filed 7–26–18; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 83, No. 145

Friday, July 27, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent To Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the U.S. Department of Agriculture, Forest Service, intends to grant to Domtar Paper Company, LLC of Fort Mill, South Carolina, an exclusive license to U.S. Patent No. 9,540,244, "METHODS FOR SYNTHESIZING GRAPHENE FROM A LIGNIN SOURCE", issued on January 10, 2017.

DATES: Comments must be received on or before August 13, 2018.

ADDRESSES: Send comments to: Thomas Moreland, Technology Transfer Coordinator, USDA Forest Service, 1400 Independence Avenue SW, Washington, DC 20250-1118, twmoreland@fs.fed.us.

FOR FURTHER INFORMATION CONTACT: Thomas Moreland, Technology Transfer Coordinator, USDA Forest Service, 443-677-6858, twmoreland@fs.fed.us.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights in this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as Domtar Paper Company, LLC of Fort Mill, South Carolina has submitted a complete and sufficient application for a license. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the

requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Mojdeh Bahar,

Assistant Administrator.

[FR Doc. 2018-16135 Filed 7-26-18; 8:45 am]

BILLING CODE 3410-03-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0049]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Emergency Management Response System

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the Emergency Management Response System.

DATES: We will consider all comments that we receive on or before September 25, 2018.

ADDRESSES: You may submit comments by either of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0049>.
- **Postal Mail/Commercial Delivery:** Send your comment to Docket No. APHIS-2018-0049, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0049> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the Emergency

Management Response System, contact Dr. Fred Bourgeois, EMRS National Coordinator, PIC, NPIC, VS, APHIS, 4700 River Road Unit 41, Riverdale, MD 20737; (318) 288-4083. For more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

SUPPLEMENTARY INFORMATION:

Title: Emergency Management Response System.

OMB Control Number: 0579-0071.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture is authorized, among other things, to protect the health of U.S. livestock and poultry populations by preventing the introduction and interstate spread of serious diseases and pests of livestock and by eradicating such diseases from the United States when feasible.

The Emergency Management Response System (EMRS), which is a web-based system, helps APHIS manage and investigate potential incidents of foreign animal diseases in the United States. When a potential foreign animal disease incident is reported, APHIS or State animal health officials dispatch a foreign animal disease veterinary diagnostician to the premises of the reported incident to conduct an investigation. The diagnostician obtains vital epidemiologic data by conducting field investigations, including sample collection, and by interviewing the owner or manager of the premises being investigated. These important data, which are submitted electronically by the diagnostician into EMRS, include such items as the purpose of the diagnostician's visit and suspected disease, type of operation on the premises, the number and type of animals on the premises, the number of sick or dead animals on the premises, the results of physical examinations of affected animals and necropsy examinations, vaccination information on the animals in the herd or flock, biosecurity practices at the site, whether any animals were recently moved out of the herd or flock, whether any new animals were recently introduced into the herd or flock, the number and kinds

of test samples taken, and detailed geographic data concerning the premises location. EMRS allows these epidemiological and diagnostic data to be documented and transmitted more efficiently.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 1 hour per response.

Respondents: Owners or operators of livestock and poultry facilities and State animal health officials.

Estimated annual number of respondents: 136.

Estimated annual number of responses per respondent: 12.

Estimated annual number of responses: 1,632.

Estimated total annual burden on respondents: 1,632 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 25th day of July 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018-16213 Filed 7-26-18; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0051]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Importation of Apples From China

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations for the importation of apples from China.

DATES: We will consider all comments that we receive on or before September 25, 2018.

ADDRESSES: You may submit comments by either of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0051>.

- **Postal Mail/Commercial Delivery:** Send your comment to Docket No. APHIS-2018-0051, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0051> or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the importation of apples from China, contact Mr. Benjamin Kaczmariski, Senior Regulatory Policy Specialist, RCC, IRM, PHP, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737; (301) 851-2127. For more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Apples From China.

OMB Control Number: 0579-0423.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. Regulations authorized by the PPA concerning the importation of fruits and vegetables into the United States from certain parts of the world are contained in "Subpart-Fruits and Vegetables" (7 CFR 319.56-1 through 319.56-83).

Under these regulations, apples from China may be imported into the continental United States under certain conditions, as listed in § 319.56-72, to prevent the introduction of plant pests into the United States. The regulations require information collection activities that include an operational workplan, production site and packinghouse registrations, tracking system, box labeling, phytosanitary certificates with declarations, inspections, investigation for detection, handling procedures, and emergency action notifications.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.022 hours per response.

Respondents: National plant protection organization of China,

production sites and packinghouses (businesses), and importers of apples.

Estimated annual number of responses: 186.

Estimated annual number of responses per respondent: 275.

Estimated annual number of responses: 51,125.

Estimated total annual burden on respondents: 1,117 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 23rd day of July 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018–16098 Filed 7–26–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0050]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Importation of Papayas From Peru

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations for the importation of papayas from Peru into the continental United States.

DATES: We will consider all comments that we receive on or before September 25, 2018.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2018-0050>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2018–0050, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket

may be viewed at <http://www.regulations.gov/#/docketDetail;D=APHIS-2018-0050> or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations related to the importation of papayas from Peru into the continental United States, contact Ms. Claudia Ferguson, Senior Regulatory Policy Coordinator, RCC, IRM, PHP, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737; (301) 851–2352. For more detailed information on the information collection, contact Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Papayas From Peru.

OMB Control Number: 0579–0410.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. As authorized by the PPA, the Animal and Plant Health Inspection Service regulates the importation of fruits and vegetables into the United States from certain parts of the world as provided in “Subpart—Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–83).

In accordance with § 319.56–25, papayas from Peru may be imported into the continental United States under certain conditions to prevent the introduction of plant pests into the United States. These conditions require the use of certain information collection activities that include applications for permits; registration of growing sites; inspections of crops, insect traps, and recordkeeping; submitting notices of arrival to ports; and responding to emergency action notifications. Also, each consignment of papayas must be accompanied by a phytosanitary certificate issued by the national plant protection organization (NPPO) of Peru containing an additional declaration stating the papayas were grown, packed,

and shipped in accordance with § 319.56–25. These actions allow the importation of papayas from Peru while continuing to protect the United States against the introduction of plant pests.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.53 hours per response.

Respondents: Growers and importers of papayas from Peru and the NPPO of Peru.

Estimated annual number of respondents: 52.

Estimated annual number of responses per respondent: 54.

Estimated annual number of responses: 2,804.

Estimated total annual burden on respondents: 1,507 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 25th day of July 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018–16210 Filed 7–26–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE**Food and Nutrition Service****Food Distribution Program: Value of Donated Foods From July 1, 2018, Through June 30, 2019**

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the national average value of donated foods or, where applicable, cash in lieu of donated foods, to be provided in school year 2019 (July 1, 2018, through June 30, 2019) for each lunch served by schools participating in the National School Lunch Program (NSLP), and for each lunch and supper served by institutions participating in the Child and Adult Care Food Program (CACFP).

DATES: July 1, 2018.

FOR FURTHER INFORMATION CONTACT:

Carolyn Smalkowski, Program Analyst, Policy Branch, Food Distribution Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, Virginia 22302-1594, or telephone (703) 305-2680.

SUPPLEMENTARY INFORMATION: These programs are located in the Assistance Listings under Nos. 10.555 and 10.558 and are subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V, and final rule related notice published at 48 FR 29114, June 24, 1983.)

This notice imposes no new reporting or recordkeeping provisions that are subject to Office of Management and Budget review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601-612) and thus is exempt from the provisions of that Act. This notice was reviewed by the Office of Management and Budget under Executive Order 12866.

National Average Minimum Value of Donated Foods for the Period July 1, 2018, Through June 30, 2019

This notice implements mandatory provisions of sections 6(c) and 17(h)(1)(B) of the Richard B. Russell National School Lunch Act (the Act) (42 U.S.C. 1755(c) and 1766(h)(1)(B)). Section 6(c)(1)(A) of the Act establishes the national average value of donated food assistance to be given to States for each lunch served in the NSLP at 11.00 cents per meal. Pursuant to section 6(c)(1)(B), this amount is subject to

annual adjustments on July 1 of each year to reflect changes in a three-month average value of the Producer Price Index for Foods Used in Schools and Institutions for March, April, and May each year (Price Index). Section 17(h)(1)(B) of the Act provides that the same value of donated foods (or cash in lieu of donated foods) for school lunches shall also be established for lunches and suppers served in the CACFP. Notice is hereby given that the national average minimum value of donated foods, or cash in lieu thereof, per lunch under the NSLP (7 CFR part 210) and per lunch and supper under the CACFP (7 CFR part 226) shall be 23.50 cents for the period July 1, 2018, through June 30, 2019.

The Price Index is computed using five major food components in the Bureau of Labor Statistics Producer Price Index (cereal and bakery products; meats, poultry, and fish; dairy; processed fruits and vegetables; and fats and oils). Each component is weighted using the relative weight as determined by the Bureau of Labor Statistics. The value of food assistance is adjusted each July 1 by the annual percentage change in a three-month average value of the Price Index for March, April, and May each year. The three-month average of the Price Index increased by 0.64 percent from 203.76 for March, April, and May of 2017, as previously published in the **Federal Register**, to 205.07 for the same three months in 2018. When computed on the basis of unrounded data and rounded to the nearest one-quarter cent, the resulting national average for the period July 1, 2018, through June 30, 2019, will be 23.50 cents per meal. This is an increase of one quarter of a cent from the school year 2018 (July 1, 2017 through June 30, 2018) rate.

Authority: Sections 6(c)(1)(A) and (B), 6(e)(1), and 17(h)(1)(B) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1755(c)(1)(A) and (B) and (e)(1), and 1766(h)(1)(B)).

Dated: July 16, 2018.

Brandon Lipps,

Administrator, Food and Nutrition Service.

[FR Doc. 2018-16028 Filed 7-26-18; 8:45 am]

BILLING CODE 3410-30-P

DEPARTMENT OF AGRICULTURE**Forest Service****Notice of New Fee Sites**

AGENCY: Idaho Panhandle National Forests, USDA Forest Service.

ACTION: Notice of new fee sites.

SUMMARY: The Idaho Panhandle National Forests is proposing to charge new fees at one day-use boat launch for \$5 per vehicle; one dump stations for \$10 per use; eight campgrounds for \$10 or \$15 per night, and an additional \$5 extra vehicle fee, starting at the third vehicle; nine boat-in campgrounds for \$15 per night; one horse camp for \$10 per night; one group campsite for \$50 per night; and two cabin/lookout rentals at \$45 or \$55 per night. These new fees would align the sites with the other sites offering similar amenities and services.

These fees are only proposed and will be determined upon further analysis and public comment.

DATES: Send any comments about these fee proposals by August 27, 2018 so comments can be compiled, analyzed, and shared with the Bureau of Land Management (BLM) Coeur d'Alene Recreation Resource Advisory Committee. The proposed effective date of implementation of proposed new fees will be no earlier than six months after publication of this notice.

ADDRESSES: Jeanne Higgins, Forest Supervisor, Idaho Panhandle National Forests, 3815 Schreiber Way, Coeur d'Alene, ID 83815 or Email to jmhiggins@fs.fed.us.

FOR FURTHER INFORMATION CONTACT: Josh Jurgensen, Forest Recreation Program Manager Idaho Panhandle National Forests at 208-765-7214 or jjurgensen@fs.fed.us. Information about proposed fee changes can also be found on the Idaho Panhandle National Forests website at <http://www.fs.usda.gov/ipnf>.

SUPPLEMENTARY INFORMATION: The Federal Recreation Lands Enhancement Act (Title VII, P.L. 108-447) directed the Secretary of Agriculture to publish a six month advance notice in the **Federal Register** whenever new recreation fee areas are established.

Once public involvement is complete, these new fees will be reviewed by the BLM Coeur d'Alene Recreation Resource Advisory Committee prior to a final decision and implementation.

Specifically, the Idaho Panhandle National Forests is proposing the following new fees:

- Beaver Creek Cabin; proposed fee of \$55 per night;
- Spyglass Ground House; proposed fee of \$45 per night;
- Big Creek, Camp 3, Line Creek Stock Camp, Packsaddle, and Telichpah campgrounds; proposed fee of \$10 per night, with an additional \$5 extra vehicle fee per night for more than two vehicles;
- Conrad Crossing, Fly Flat, Mammoth Springs, and Spruce Tree campgrounds; proposed fee of \$15 per

night, with an additional \$5 extra vehicle fee per night for more than two vehicles;

- Bottle Bay, Geisinger, Navigation, Plowboy, Teacher Bay, Trapper, and Tule Bay Boat-in campgrounds on Priest Lake; proposed fee of \$15 per night;
- Green Bay and Whiskey Rock boat-in campgrounds on Pend Oreille Lake; proposed fee of \$15 per night;
- Reynolds Creek Group camp site; proposed fee of \$50 per night;
- Shadowy St. Joe Day Use Boating site; proposed fee of \$5 per vehicle, per day;
- Priest Lake Information Site (RV Dump Station); proposed fee of \$10 per use.

Additional construction is required at the Spyglass Ground House to complete the renovation project and it is anticipated that this site would be available for the public to rent in May of 2019. The Beaver Creek Cabin is currently unfurnished and would be available to rent in 2018 for \$45 per night; however, once the cabin is furnished the fee would be raised to \$55 per night.

Reasonable fees, paid by users of these sites and services, will help ensure that the Forest can continue maintaining and improving the sites for future generations. A market analysis of surrounding recreation sites with similar amenities indicates that the proposed fees are comparable and reasonable.

Advance reservations for the Beaver Creek Cabin, Lunch Peak Lookout, and Spyglass Ground House will be available through www.recreation.gov or by calling 1-877-444-6777. The reservation service charges a \$10 fee for reservations.

Dated: January 10, 2018.

Chris French,

Associate Deputy Chief, National Forest System.

Editorial Note: This document was received for publication by the Office of the Federal Register on July 23, 2018.

[FR Doc. 2018-16032 Filed 7-26-18; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture Service

[Docket No. NIFA-2018-003]

Notice of Intent for Renewal of a Currently Approved Information Collection

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, which implemented the Paperwork Reduction Act of 1995, this notice announces the National Institute of Food and Agriculture's (NIFA's) intention to request an extension for a currently approved information collection (OMB No. 0524-0026) for Form NIFA-666, "Organizational Information."

DATES: Written comments on this notice must be received by September 25, 2018 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments concerning this notice and requests for copies of the information collection may be submitted to Robert Martin, Records Officer, Information Policy, Planning and Training, Office of Information Technology (OIT), NIFA/USDA; Mail Stop 2216; 1400 Independence Avenue SW; Washington, DC 20250-2299; Hand Delivery/Courier: 800 9th Street SW, Waterfront Centre, Room 4206, Washington, DC 20024; or Email: rmartin@nifa.usda.gov.

FOR FURTHER INFORMATION CONTACT: Robert Martin, Records Officer, Information Policy, Planning and Training, Office of Information Technology, NIFA/USDA, Email: rmartin@nifa.usda.gov.

SUPPLEMENTARY INFORMATION:

Title of Collection: Organizational Information.

OMB Control Number: 0524-0026.

Expiration Date of Current Approval: October 30, 2018.

Type of Request: Intent to extend a currently approved information collection for three years.

Abstract: NIFA has primary responsibility for providing linkages between the Federal and State components of a broad-based, national agricultural research, extension, and education system. Focused on national issues, its purpose is to represent the Secretary of Agriculture and carry out the intent of Congress by administering capacity and grant funds appropriated for agricultural research, extension, and education. Before awards can be made, certain information is required from applicants to effectively assess the potential recipient's capacity to manage Federal funds.

Need and Use of the Information: Form NIFA-666 "Organizational Information": Enables NIFA to

determine that the applicants recommended for awards will be responsible recipients of Federal funds. The information requested from the applicant pertains to the organizational and financial management of the potential grantee. This form and the attached applicant documents provide NIFA with information such as the legal name of the organization, certification that the organization has the legal authority to accept Federal funding, identification and signatures of the key officials, the organization's policies for employee compensation and benefits, equipment insurance, policies on subcontracting with other organizations, etc., as well the financial condition of the organization and certification that the organization is not delinquent on Federal taxes. All of this information is considered prior to award, to determine the grantee is both managerially and fiscally responsible. This information is submitted to NIFA on a one-time basis and updated accordingly. If sufficient changes occur within the organization, the grantee submits revised information.

Estimate of the Burden: NIFA estimates the number of responses for the Form NIFA-666 will be 150 with an estimated response time of 6.3 hours per form, representing a total annual burden of 945 hours for this form. These estimates are based on a survey of grantees that were approved for grant awards.

They were asked to give an estimate of time it took them to complete each form. This estimate was to include such things as: (1) Reviewing the instructions; (2) searching existing data sources; (3) gathering and maintaining the data needed; and (4) actual completion of the forms. The average time it took each respondent was calculated from their responses.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have a practical utility;

(b) the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Done at Washington, DC, this 19th day of July 2018.

Chavonda Jacobs-Young,

Acting Under Secretary for Research, Education and Economics.

[FR Doc. 2018–16100 Filed 7–26–18; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Broadband e-Connectivity Pilot Program

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of inquiry and request for comments.

SUMMARY: The Rural Utilities Service (RUS), an agency of the United States Department of Agriculture, invites comment on the implementation of certain provisions of its pilot broadband program (e-Connectivity Pilot) established on March 23, 2018, in the Consolidated Appropriations Act of 2018. The e-Connectivity Pilot was appropriated \$600 million in budget authority to be operated under the Rural Electrification Act of 1936 on an expedited basis. Loans and grants are limited to the costs of the construction, improvement, and acquisition of facilities and equipment for broadband service in eligible communities.

DATES: Comments are due on or before 5 p.m. Eastern Daylight Time on September 10, 2018.

ADDRESSES: Submit comments, identified as *e-Connectivity Pilot*, by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and, in the lower “Search Regulations and Federal Actions” box, select “Rural Utilities Service” from the agency drop-down menu, then click on “Submit.” In the Docket ID column, select RUS–18–TELECOM–0004 to submit or view public comments and to view supporting and related materials available electronically. Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site’s “User Tips” link.

- *Postal Mail/Commercial Delivery:* Please send your comment addressed to Michele Brooks, Rural Development Innovation Center, Regulations Team Lead, U.S. Department of Agriculture, 1400 Independence Ave. SW, Stop 1522, Room 1562, Washington, DC

20250. Please state that your comment refers to Docket No. RUS–18–TELECOM–0004.

Other Information: Additional information about Rural Development and its programs is available on the internet at <https://www.usda.gov/topics/rural>.

SUPPLEMENTARY INFORMATION: Section 779 of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141) appropriated \$600 million for a pilot broadband program (e-Connectivity Pilot) to be operated under the Rural Electrification Act (RE Act) of 1936 (7 U.S.C. 901 *et seq.*). The e-Connectivity Pilot was directed to expedite loans and grants for the costs of the construction, improvement, and acquisition of facilities and equipment for broadband service in eligible rural areas. Those areas are defined as having at least 90 percent of the households without sufficient access to broadband, defined as 10 Mbps downstream, and 1 Mbps upstream. Applications for eligible rural areas are prohibited from over-building or duplicating broadband expansion efforts made by any entity that has received a broadband loan from the Rural Utilities Service. Applications must also be evaluated by the service area assessment requirements of Section 601(d)(10) of the RE Act (7 U.S.C. 950bb(d)(10)) so that existing broadband providers may provide input on service in the proposed service area. In the absence of responses, RUS is directed to use the most current data of the National Broadband Map, or any other data regarding the availability of broadband service that may be collected or obtained through reasonable efforts.

Notice of Inquiry and Request for Comment

RUS seeks input on several questions concerning development of the e-Connectivity Pilot. Comments are requested from a broad range of stakeholders with an interest in rural broadband deployment. Specifically, RUS seeks comment on the following:

(1) Eligible rural areas are defined as having at least 90 percent of the households without *sufficient access* to broadband, defined in the law as 10 Mbps downstream, and 1 Mbps upstream. At present, RUS is working to determine what types of technologies and services are defined as “sufficient access.” In particular, RUS is seeking information about the transmission capacity required for economic development, and speed and latency, especially in peak usage hours, to ensure rural premises have access to

coverage similar to that offered in urban areas. Comments are specifically requested on whether affordability of service should be included in evaluating whether an area already has “sufficient access” and how to benchmark affordability of internet services. And if so, what equates to consumers’ costs being so high that they are effectively rendered inaccessible to rural households? Further, what other elements should RUS consider when defining sufficient access?

(2) RUS uses a combination of a Public Notice Filing—Public Notice Response process through our online mapping tool and the most current data of the National Broadband Map, or any other data regarding the availability of broadband service that may be collected or obtained through reasonable efforts. RUS’ mapping tool will publicly post proposed service territories of applicants to allow existing service providers an opportunity to comment if 10 Mbps downstream and 1 Mbps upstream service exists for households in the proposed service area or not. Notwithstanding this data, comments are sought on how data speeds are to be used or verified, given the limited availability of publicly-available information regarding accurate broadband speeds provided to rural households. Additionally, what other sources of data availability should be used for evaluation?

(3) RUS is working to ensure that projects funded by the e-Connectivity pilot provide improvements to rural prosperity. This includes projects that benefit rural industries such as agriculture, manufacturing, e-commerce, transportation, health care, and education. Comments are specifically requested on effective methods that can measure leading indicators of potential project benefits for these sectors, using readily available public data. USDA is also aiming to improve rural economies, especially for those being served. Comments are also being sought on how to evaluate the viability of applications that include local utility partnership arrangements, including locally-owned telecommunications companies where possible.

Dated: July 17, 2018.

Jonathan P. Claffey,

Senior Policy Advisor, Rural Utilities Service.

[FR Doc. 2018–16014 Filed 7–26–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE**Bureau of the Census****Request for Nominations of Members To Serve on the National Advisory Committee on Racial, Ethnic, and Other Populations; Extension of Nominations Submission Period**

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of request for nominations; extension of nominations submission period.

SUMMARY: The Bureau of the Census (Census Bureau) is issuing this document to extend the nominations submission period for the Request for Nominations of Members to Serve on the National Advisory Committee on Racial, Ethnic, and Other Populations, which was published in the **Federal Register** on June 4, 2018. The extension is in response to public demand for more time to submit nominations for the Committee. The nominations submission period, which would have ended on August 3, 2018, is now extended until September 4, 2018.

DATES: Nomination submissions on the notice of request for nominations published on June 4, 2018 (83 FR 25643) must be received by September 4, 2018. The Census Bureau will retain nominations received after this date for consideration should additional vacancies occur.

ADDRESSES: Please submit nominations to the *census.national.advisory.committee@census.gov* (subject line “2018 NAC Nominations”) or by letter submission to Tara Dunlop Jackson, Committee Liaison Officer, 2018 NAC Nominations, Department of Commerce, U.S. Census Bureau, Room 8H177, 4600 Silver Hill Road, Washington, DC 20233.

FOR FURTHER INFORMATION CONTACT: Tara Dunlop Jackson, Committee Liaison Officer, Customer Liaison Marketing Services Office, U.S. Census Bureau, Room 8H177, 4600 Silver Hill Road, Washington, DC 20233, at (301) 763-5222 or *census.national.advisory.committee@census.gov*. For TTY callers, please use the Federal Relay Service at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:**Background**

The National Advisory Committee on Racial, Ethnic, and Other Populations was established in accordance with the Federal Advisory Committee Act (FACA), Title 5, United States Code, Appendix 2. For more information about the Committee, membership, and

the nomination process, please see the original document on the notice of request for nominations published on June 4, 2018 (83 FR 25643).

In response to individuals and organizations who have requested more time to submit nominations of members to serve on the Committee, the Census Bureau has decided to extend the nominations submission period to September 4, 2018. This document announces the extension of the nominations submission period.

Dated: July 20, 2018.

Ron S. Jarmin,

Associate Director for Economic Programs, Performing the Non-Exclusive Functions and Duties of the Director, Bureau of the Census.

[FR Doc. 2018-16020 Filed 7-26-18; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE**Bureau of the Census****Request for Nominations of Members To Serve on the Census Scientific Advisory Committee**

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of request for nominations.

SUMMARY: The Bureau of the Census (Census Bureau) requests nominations of individuals to the Census Scientific Advisory Committee. The Census Bureau will consider nominations received in response to this notice, as well as from other sources. The **SUPPLEMENTARY INFORMATION** section of this notice provides Committee and membership criteria.

DATES: Please submit nominations by September 25, 2018. The Census Bureau will retain nominations received after this date for consideration should additional vacancies occur.

ADDRESSES: Please submit nominations to the *census.scientific.advisory.committee@census.gov* (subject line “2018 CSAC Nominations”) or by letter submission to Tara Dunlop Jackson, Committee Liaison Officer, 2018 CSAC Nominations, Department of Commerce, U.S. Census Bureau, Room 8H177, 4600 Silver Hill Road, Washington, DC 20233.

FOR FURTHER INFORMATION CONTACT: Tara Dunlop Jackson, Branch Chief for Advisory Committees, Customer Liaison and Marketing Services Office, Department of Commerce, U.S. Census Bureau, Room 8H177, 4600 Silver Hill Road, Washington, DC 20233, (301) 763-5222 or *census.scientific.advisory.committee@census.gov*.

SUPPLEMENTARY INFORMATION: The Census Scientific Advisory Committee was established in accordance with the Federal Advisory Committee Act (FACA), Title 5, United States Code (U.S.C.), Appendix 2. The following provides information about the Committee, membership, and the nomination process.

Objectives and Duties

1. The Census Scientific Advisory Committee advises the Director of the U.S. Census Bureau on the uses of scientific developments in statistical data collection, statistical analysis, survey methodology, geospatial analysis, econometrics, cognitive psychology, and computer science as they pertain to the full range of Census Bureau programs and activities (including: Communications, decennial, demographic, economic, field operations, geographic, information technology, and statistics).

2. The Census Scientific Advisory Committee provides scientific and technical expertise from the following disciplines: Demography, economics, geography, psychology, statistics, survey methodology, social and behavioral sciences, Information Technology and computing, marketing, communications, and other fields of expertise, as appropriate, to address Census Bureau program needs and objectives. This expertise is necessary to ensure that the Census Bureau continues to provide relevant and timely statistics used by tribal, federal, state, and local governments as well as business and industry in an increasingly technologically-oriented society.

3. The Census Scientific Advisory Committee functions solely as an advisory body under the FACA.

4. The Census Scientific Advisory Committee reports to the Director of the Census Bureau.

Membership

1. The Census Scientific Advisory Committee consists of up to 21 members and one Chair appointed by the Director of the Census Bureau. The Census Bureau is currently filling five seats.

2. Members are appointed for a three-year term.

3. Members shall serve as Special Government Employees (SGEs) and will be subject to the ethical standards applicable to SGEs. Committee membership will be reevaluated at the conclusion of the three-year term. Member renewal will be based on active attendance, participation in meetings, administrative compliance, Census Bureau needs, and the Director's concurrence.

4. Committee members are selected in accordance with applicable Department of Commerce guidelines. The Census Scientific Advisory Committee aims to have balanced representation, considering such factors as geography and technical and scientific expertise. The Committee will include members from diverse backgrounds, including academia and private enterprise, which are further diversified by business type or industry, geography, and other factors.

5. No employee of the federal government can serve as a member of the Census Scientific Advisory Committee.

Miscellaneous

1. Members of the Census Scientific Advisory Committee serve without compensation, but receive reimbursement for Committee-related travel and lodging expenses.

2. The Census Scientific Advisory Committee meets once or twice a year, budget permitting. Additional meetings may be held as deemed necessary by the Census Bureau Director or Designated Federal Official. All Committee meetings are open to the public in accordance with the FACA.

Nomination Information

1. Nominations are requested as described above.

2. Nominees must have scientific and technical expertise in such areas as demography, economics, geography, psychology, statistics, survey methodology, social and behavioral sciences, Information Technology, computing, or marketing. Such knowledge and expertise are needed to provide advice and recommendations to the Director of the Census Bureau on the trends, uses, and application of scientific innovations and developments in relation to the full range of Census Bureau programs and activities.

3. The Census Bureau is especially interested in receiving applications from persons with expertise in demography, statistics, business/finance, sociology, and marketing.

4. Individuals, groups, and/or organizations may submit nominations on behalf of individual candidates. A summary of the candidate's qualifications (resumé or curriculum vitae) must be included along with the nomination letter. Nominees must be able to actively participate in the tasks of the Census Scientific Advisory Committee, including, but not limited to, regular meeting attendance, Committee meeting discussion responsibilities, review of materials, as well as participation in conference calls,

webinars, working groups, and/or special Committee activities.

5. The Department of Commerce is committed to equal opportunity in the workplace and seeks diverse Committee membership.

Dated: July 20, 2018.

Ron S. Jarmin,

*Associate Director for Economic Programs,
Performing the Non-Exclusive Functions and
Duties of the Director, Bureau of the Census.*

[FR Doc. 2018-16021 Filed 7-26-18; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S-103-2018]

Foreign-Trade Zone 93—Raleigh/ Durham, North Carolina; Application for Subzone; MAS US Holdings, Inc.; Siler City and Asheboro, North Carolina

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Triangle J Council of Governments, grantee of FTZ 93, requesting subzone status for the facilities of MAS US Holdings, Inc., located in Siler City and Asheboro, North Carolina. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on July 23, 2018.

The proposed subzone would consist of the following sites: *Site 1* (40.4 acres) 1311 Eleventh Street, Siler City, Chatham County; *Site 2* (21.74 acres) 601 East Pritchard Street, Asheboro, Randolph County; and, *Site 3* (3.46 acres) 162 North Cherry Street, Asheboro, Randolph County. No authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 93.

In accordance with the FTZ Board's regulations, Kathleen Boyce of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is September 5, 2018. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to September 20, 2018.

A copy of the application will be available for public inspection at the

Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230-0002, and in the "Reading Room" section of the FTZ Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Kathleen Boyce at Kathleen.Boyce@trade.gov or (202) 482-1346.

Dated: July 23, 2018.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2018-16077 Filed 7-26-18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-964]

Seamless Refined Copper Pipe and Tube From the People's Republic of China: Rescission of Antidumping Duty Administrative Review; 2016- 2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding its administrative review of the antidumping duty order on seamless refined copper pipe and tube (copper pipe and tube) from the People's Republic of China (China) for the period of review (POR) November 1, 2016, through October 31, 2017.

DATES: Applicable July 27, 2018.

FOR FURTHER INFORMATION CONTACT: Maisha Cryor AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-5831.

SUPPLEMENTARY INFORMATION:

Background

On November 1, 2017, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on copper pipe and tube from China for the period November 1, 2016, through October 31, 2017.¹ On November 21, 2017, the Ad Hoc Coalition for Domestically Produced Seamless Refined Copper Pipe

¹ See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review*, 82 FR 50620 (November 1, 2017).

and Tube and its individual members² (collectively, the petitioners), timely requested that Commerce conduct an administrative review of this antidumping duty order with respect to Golden Dragon Precise Copper Tube Group, Inc. (Golden Dragon).³ On January 11, 2018, Commerce initiated an administrative review with respect to Golden Dragon, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.221(c)(1)(i).⁴ On March 29, 2018, the petitioners timely withdrew their request for an administrative review.⁵

Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested a review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. In this case, the petitioners withdrew their request for review by the 90-day deadline. Because Commerce received no other request for a review of the antidumping duty order with respect to Golden Dragon, and no other requests were made for a review of the antidumping duty order with respect to other companies, we are rescinding this administrative review covering the period November 1, 2016, through October 31, 2017, in accordance with 19 CFR 213(d)(1).

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of copper pipe and tube from China during the POR. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice in the **Federal Register**.

² The individual members of Ad Hoc Coalition for Domestically Produced Seamless Refined Copper Pipe and Tube are Cerro Flow Products, LLC, Wieland Copper Products, LLC, Howell Metal Company, Mueller Copper Tube Products, Inc., and Mueller Copper Tube Company, Inc.

³ See Letter from the petitioners, "Seamless Refined Copper Pipe and Tube from China: Request for Antidumping Duty Administrative Review," dated November 21, 2017.

⁴ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 82 FR 1329, 1333 (January 11, 2018).

⁵ See Letter from the petitioners, "Seamless Refined Copper Pipe and Tube from China: Withdrawal of Request for Antidumping Duty Administrative Review," dated March 29, 2018.

Notification to Importers

This notice serves as the only reminder to importers of their responsibility, under 19 CFR 351.402(f)(2), to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: July 20, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018-16075 Filed 7-26-18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Annual U.S. Industry Program at the International Atomic Energy Agency (IAEA) General Conference; Meeting

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of 11th Annual U.S. Industry Program at the International Atomic Energy Agency (IAEA) General Conference.

Mission Description

The United States Department of Commerce's (DOC) International Trade Administration (ITA), with participation

from the U.S. Departments of Energy and State, is organizing the 11th Annual U.S. Industry Program at the International Atomic Energy Agency (IAEA) General Conference, to be held September 16–19, 2018, in Vienna, Austria. The IAEA General Conference is the premier global meeting of civil nuclear policymakers and typically attracts senior officials and industry representatives from all 162 Member States. The U.S. Industry Program is part of the U.S. Department of Commerce's (DOC) Civil Nuclear Trade Initiative, a U.S. Government effort to help U.S. civil nuclear companies identify and capitalize on commercial civil nuclear opportunities around the world. The purpose of the program is to help the U.S. nuclear industry promote its services and technologies to an international audience, including senior energy policymakers from current and emerging markets as well as IAEA staff.

Representatives of U.S. companies from across the U.S. civil nuclear supply chain are eligible to participate. In addition, organizations providing related services to the industry, such as universities, research institutions, and U.S. civil nuclear trade associations, are eligible for participation. The mission will help U.S. participants gain market insights, make industry contacts, solidify business strategies, and identify or advance specific projects with the goal of increasing U.S. civil nuclear exports to a wide variety of countries interested in nuclear energy.

The schedule includes: Meetings with foreign delegations and discussions with senior U.S. Government officials on important civil nuclear topics including regulatory, technology and standards, liability, public acceptance, export controls, financing, infrastructure development, and R&D cooperation. Past U.S. Industry Programs have included participation by the U.S. Secretary of Energy, the Chairman of the U.S. Nuclear Regulatory Commission (NRC) and senior U.S. Government officials from the Departments of Commerce, Energy, State, the Export-Import Bank of the United States and the National Security Council.

There are significant opportunities for U.S. businesses in the global civil nuclear energy market. With 55 reactors currently under construction in 15 countries and 160 nuclear plant projects planned in 27 countries over the next 8–10 years, this translates to a market demand for equipment and services totaling \$500–740 billion over the next ten years. This mission contributes to DOC's Civil Nuclear Trade Initiative by assisting U.S. businesses in entering or expanding in international markets.

Mission Setting

The IAEA General Conference is the premier global meeting of civil nuclear policymakers, and typically attracts over 1,200 senior officials and industry representatives from all 162 IAEA Member States. As such, it is an opportunity to highlight the breadth and depth of the U.S. civil nuclear sector to foreign energy policymakers and potential customers. The U.S. Industry Program will provide opportunities for U.S. industry representatives to meet with U.S. Government representatives and discuss key issues of interest for civil nuclear exporters. The program will also feature briefings from foreign government representatives, providing opportunities for participants to develop contacts in potential export markets.

Mission Goals

The purpose of the U.S. Industry Program is to highlight the benefits of U.S. civil nuclear technology to foreign decision makers in key export markets and to enable representatives from the U.S. public and private sector to discuss U.S. industry's role in the safe and secure expansion of civil nuclear power worldwide. U.S. participants will also have the opportunity to network and build relationships in the global civil nuclear sector, interact with foreign government and industry officials, and learn more about current and future project opportunities. Foreign government participants will hear about the expertise that U.S. industry has amassed in this sector and may learn how to better partner with U.S. industry on future nuclear power projects.

Mission Scenario

On Sunday September 16, trade mission participants will have one-on-one meetings with visiting ITA staff from top export markets as part of ITA's Showtime Program (meetings are subject to availability of visiting ITA staff) and an evening U.S. Industry Welcome Reception. On Monday, September 17, mission participants will begin with a Policymaker's Roundtable and an interagency U.S. Government briefing featuring discussion sessions and remarks by senior officials from the U.S. Departments of Commerce, Energy and State, and the NRC. In addition, on Monday, Tuesday, and Wednesday, meetings with foreign delegation officials from some of the top markets for U.S. civil nuclear exports will be scheduled. Approximately ten such meetings will be planned throughout the duration of the event. Throughout the weeklong conference, participants can attend IAEA side meetings using

their official IAEA badges, which will be provided as part of the program.

Event Dates and Proposed Agenda

****Note that specific events and meeting times have yet to be confirmed****

Sunday, September 16

3:00 p.m.–5:00 p.m. 1–1 Showtime Meetings with visiting ITA Staff
6:00 p.m.–8:00 p.m. U.S. Industry Welcome Reception

Monday, September 17

7:00 a.m. Industry Program Breakfast Begins
8:00–9:45 a.m. U.S. Policymakers Roundtable
9:45–10:00 a.m. Break
10:00–11:00 a.m. USG Dialogue with Industry
11:00 a.m.–6:00 p.m. IAEA Side Events
11:00 a.m.–12:30 p.m. Break
12:30–6:00 p.m. Country Briefings for Industry (presented by foreign delegates)
7:30–9:30 p.m. U.S. Mission to the IAEA Reception

Tuesday, September 18

9:00 a.m.–6:00 p.m. Country Briefings for Industry (presented by foreign delegates)
10:00 a.m.–6:00 p.m. IAEA Side Event Meetings

Wednesday, September 19

9:00 a.m.–6:00 p.m. Country Briefings for Industry (presented by foreign delegates)
10:00 a.m.–6:00 p.m. IAEA Side Event Meetings

Participation Requirements

Applicants must sign and submit a completed Trade Mission application form and satisfy all of the conditions of participation in order to be eligible for consideration. Applications will be evaluated on the applicant's ability to best satisfy the participation criteria. A minimum of 15 and maximum of 50 companies and/or trade associations and/or U.S. academic and research institutions will be selected to participate in the mission. The first fifteen applicants will be permitted to send two representatives per organization (if desired). After the first fifteen applicants, additional representatives will be permitted only if space is available. The Department of Commerce will evaluate applications and inform applicants of selection decisions [three weeks after publication in the **Federal Register**] and on a rolling basis thereafter until the maximum

number of participants has been selected.

Conditions for Participation

Applicants must submit a completed mission application signed by a company, trade association, or academic or research institution official, together with supplemental application materials, including adequate information on the organization's products and/or services, primary market objectives, and goals for participation. If the DOC receives an incomplete application, the DOC may reject the application, request additional information, or take the lack of information into account in its evaluation.

Each applicant must certify one's organization is not majority-owned or -controlled by a foreign government entity (or foreign government entities). Each applicant also must certify that the products or services it seeks to export through the mission are either produced in the United States, or, if not, marketed under the name of a U.S. firm and have demonstrable U.S. content as a percentage of the value of the finished product or service. In the case of a trade association, the applicant must certify that it will only be representing companies during the Trade Mission consistent with the domestic content criteria laid out in this section. In the case of an academic or research institution, the applicant must certify that as part of its activities at the event, it will represent the interests of the organization's staff that meet the criteria above.

Applicants must:

- Certify that the products and services that it wishes to market through the mission would be in compliance with U.S. export controls and regulations;
- Certify that it has identified any matter pending before any bureau or office in the U.S. Department of Commerce;
- Certify that it has identified any pending litigation (including any administrative proceedings) to which it is a party that involves the U.S. Department of Commerce;
- Sign and submit an agreement that it and its affiliates (1) have not and will not engage in the bribery of foreign officials in connection with a company's/participant's involvement in this mission, and (2) maintain and enforce a policy that prohibits the bribery of foreign officials; and
- Certify that it meets the minimum requirements as stated in this announcement.

Applicants from a company, organization or institution that is majority-owned or -controlled by a foreign government entity will not be considered for participation in the U.S. Industry Program.

Selection Criteria

Selection will be based on the following criteria:

- Suitability of the company's (or, in the case of another organization, represented companies' or constituents') products or services to each of the markets the company or organization has expressed an interest in exporting to as part of this trade mission.

- The company's (or, in the case of another organization, represented companies' or constituents') potential for business in each of the markets the company or organization has expressed an interest in exporting to as part of this trade mission, including likelihood of exports resulting from the mission.

- Consistency of the applicant company's (or, in the case of another organization, represented companies' or constituents') goals and objectives with the stated mission scope.

Referrals from political organizations and any documents containing references to partisan political activities (including political contributions) will be removed from an applicant's submission and will not be considered.

Timeframe for Recruitment and Participation

Recruitment for participation in the U.S. Industry Program as a representative of the U.S. civil nuclear industry will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the DOC trade mission calendar, notices to industry trade associations and other multiplier groups. Recruitment will begin after publication in the **Federal Register** and conclude no later than August 3, 2018. The ITA will review applications and make selection decisions on a rolling basis thereafter. Applications received after August 3, 2018, will be considered only if space and scheduling permit.

Fees and Expenses

After a company or organization has been selected to participate on the mission, a payment to the DOC in the form of a participation fee is required. The fee covers ITA support to register U.S. industry participants for the IAEA General Conference. Participants will be able to take advantage of discounted rates for hotel rooms.

- The fee to participate in the event is \$2,700 for a large company and

\$2,266 for a small or medium-sized company (SME), a trade association, or a U.S. university or research institution. The fee for each additional representative (large company, trade association, university/research institution, or SME) is \$1,100.

- To apply to the mission, complete the trade mission application at <https://emenuapps.ita.doc.gov/ePublic/TM/8ROV>.

Participants selected for the Trade Mission will be expected to pay for the cost of all personal expenses, including, but not limited to, international travel, lodging, meals, transportation, communication, and incidentals, unless otherwise noted. In the event that the Mission is canceled, no personal expenses paid in anticipation of a Trade Mission will be reimbursed. However, participation fees for a canceled Trade Mission will be reimbursed to the extent they have not already been expended in the anticipation of the Mission.

Contacts

Jonathan Chesebro, DOC, ITA, Industry & Analysis, Office of Energy and Environmental Industries, Washington, DC, Tel: (202) 482-1297, Email: jonathan.chesebro@trade.gov.

Devin Horne, DOC, ITA, Industry & Analysis, Office of Energy and Environmental Industries, Washington, DC, Tel: (202) 482-0775, Email: devin.horne@trade.gov.

Dated: July 23, 2018.

Man Cho,

Deputy Director, Office of Energy and Environmental Industries.

[FR Doc. 2018-16099 Filed 7-26-18; 8:45 am]

BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-967]

Aluminum Extrusions From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2016-2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty order on aluminum extrusions from the People's Republic of China (China) for the period of review (POR) May 1, 2016, through April 30, 2017. We determine that 25 of the

companies for which an administrative review was requested, and not withdrawn, failed to demonstrate eligibility for a separate rate; therefore, each is part of the China-wide entity. We also determine that Guangdong Xin Wei Aluminum Products Co., Ltd., Xin Wei Aluminum Company Limited, and Xin Wei Aluminum Co. Ltd. made no entries, exports, or sales of the subject merchandise during the POR covered by this administrative review.

DATES: Applicable July 27, 2018.

FOR FURTHER INFORMATION CONTACT:

Deborah Scott or Mark Flessner, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-2657 or (202) 482-6312, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce initiated this review on July 6, 2017.¹ On February 8, 2018, Commerce published the *Preliminary Results* of this administrative review.² At that time, we invited interested parties to comment on the *Preliminary Results*.³ On March 13, 2018, we received case briefs from the Aluminum Extrusions Fair Trade Committee (the petitioner)⁴ and Xin Wei Aluminum Company Limited, Guangdong Xin Wei Aluminum Products Co., Ltd., Xin Wei Aluminum Co. Ltd., Xin Wei Aluminum Co., and Regal Ideas Inc. (collectively, Xin Wei/Regal).⁵ On March 19, 2018, we received rebuttal briefs from the petitioner⁶ and Tai-Ao Aluminium (Taishan) Co., Ltd. (Tai-Ao).⁷ No other party submitted case or rebuttal briefs. These final results cover 29 companies

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 82 FR 31292 (July 6, 2017) (*Initiation Notice*).

² See *Aluminum Extrusions from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Rescission of Review in Part; 2016-2017*, 83 FR 5604 (February 8, 2018) (*Preliminary Results*) and accompanying preliminary decision memorandum (Preliminary Decision Memorandum).

³ See *Preliminary Results*, 83 FR at 5606; see also 19 CFR 351.309.

⁴ See Petitioner Letter re: Aluminum Extrusions from the People's Republic of China: Case Brief, dated March 13, 2018.

⁵ See Xin Wei/Regal Letter re: Aluminum Extrusions from the People's Republic of China: Case Brief, dated March 13, 2018.

⁶ See Petitioner Letter re: Aluminum Extrusions from the People's Republic of China: Rebuttal Brief, dated March 19, 2018.

⁷ See Tai-Ao Letter re: Tai-Ao's Administrative Rebuttal Brief: Administrative Review of the Antidumping Duty Order on Aluminum Extrusions from the People's Republic of China: Review Period—5/1/16-4/30/17, dated March 19, 2018.

for which an administrative review was initiated and not rescinded.⁸

Scope of the Order

The merchandise covered by the Order⁹ is aluminum extrusions which are shapes and forms, produced by an extrusion process, made from aluminum alloys having metallic elements corresponding to the alloy series designations published by The Aluminum Association commencing with the numbers 1, 3, and 6 (or proprietary equivalents or other certifying body equivalents).¹⁰

Imports of the subject merchandise are provided for under the following categories of the Harmonized Tariff Schedule of the United States (HTSUS): 6603.90.8100, 7616.99.51, 8479.89.94, 8481.90.9060, 8481.90.9085, 9031.90.9195, 8424.90.9080, 9405.99.4020, 9031.90.90.95, 7616.10.90.90, 7609.00.00, 7610.10.00, 7610.90.00, 7615.10.30, 7615.10.71, 7615.10.91, 7615.19.10, 7615.19.30, 7615.19.50, 7615.19.70, 7615.19.90, 7615.20.00, 7616.99.10, 7616.99.50, 8479.89.98, 8479.90.94, 8513.90.20, 9403.10.00, 9403.20.00, 7604.21.00.00, 7604.29.10.00, 7604.29.30.10, 7604.29.30.50, 7604.29.50.30, 7604.29.50.60, 7608.20.00.30, 7608.20.00.90, 8302.10.30.00, 8302.10.60.30, 8302.10.60.60, 8302.10.60.90, 8302.20.00.00, 8302.30.30.10, 8302.30.30.60, 8302.41.30.00, 8302.41.60.15, 8302.41.60.45, 8302.41.60.50, 8302.41.60.80, 8302.42.30.10, 8302.42.30.15, 8302.42.30.65, 8302.49.60.35, 8302.49.60.45, 8302.49.60.55, 8302.49.60.85, 8302.50.00.00, 8302.60.90.00, 8305.10.00.50, 8306.30.00.00, 8414.59.60.90, 8415.90.80.45, 8418.99.80.05, 8418.99.80.50, 8418.99.80.60, 8419.90.10.00, 8422.90.06.40, 8473.30.20.00, 8473.30.51.00, 8479.90.85.00, 8486.90.00.00, 8487.90.00.80, 8503.00.95.20, 8508.70.00.00, 8515.90.20.00, 8516.90.50.00,

8516.90.80.50, 8517.70.00.00, 8529.90.73.00, 8529.90.97.60, 8536.90.80.85, 8538.10.00.00, 8543.90.88.80, 8708.29.50.60, 8708.80.65.90, 8803.30.00.60, 9013.90.50.00, 9013.90.90.00, 9401.90.50.81, 9403.90.10.40, 9403.90.10.50, 9403.90.10.85, 9403.90.25.40, 9403.90.25.80, 9403.90.40.05, 9403.90.40.10, 9403.90.40.60, 9403.90.50.05, 9403.90.50.10, 9403.90.50.80, 9403.90.60.05, 9403.90.60.10, 9403.90.60.80, 9403.90.70.05, 9403.90.70.10, 9403.90.70.80, 9403.90.80.10, 9403.90.80.15, 9403.90.80.20, 9403.90.80.41, 9403.90.80.51, 9403.90.80.61, 9506.11.40.80, 9506.51.40.00, 9506.51.60.00, 9506.59.40.40, 9506.70.20.90, 9506.91.00.10, 9506.91.00.20, 9506.91.00.30, 9506.99.05.10, 9506.99.05.20, 9506.99.05.30, 9506.99.15.00, 9506.99.20.00, 9506.99.25.80, 9506.99.28.00, 9506.99.55.00, 9506.99.60.80, 9507.30.20.00, 9507.30.40.00, 9507.30.60.00, 9507.90.60.00, and 9603.90.80.50.

The subject merchandise entered as parts of other aluminum products may be classifiable under the following additional Chapter 76 subheadings: 7610.10, 7610.90, 7615.19, 7615.20, and 7616.99, as well as under other HTSUS chapters. In addition, fin evaporator coils may be classifiable under HTSUS numbers: 8418.99.80.50 and 8418.99.80.60. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this Order is dispositive.¹¹

Analysis of Comments Received

All issues raised in the case briefs filed by parties in this review are addressed in the Issues and Decision Memorandum, which is incorporated herein by reference. A list of the issues which any party raised, and to which we respond in the Issues and Decision Memorandum, follows in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov> and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at

<http://enforcement.trade.gov/frn/index.html>. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of the comments received, and for the reasons explained in the Issues and Decision Memorandum, we made certain changes to the treatment of Guangdong Xin Wei Aluminum Products Co., Ltd., Xin Wei Aluminum Company Limited, and Xin Wei Aluminum Co. Ltd.¹²

Final Determination of No Shipments

We find that a certification of no shipments on behalf of Guangdong Xin Wei Aluminum Products Co., Ltd., Xin Wei Aluminum Company Limited, and Xin Wei Aluminum Co. Ltd. satisfied the requirements of section 351.213(d)(3) of Commerce's regulations that there were no entries, exports, or sales of the subject merchandise during the POR. Therefore, we determine that Guangdong Xin Wei Aluminum Products Co., Ltd., Xin Wei Aluminum Company Limited, and Xin Wei Aluminum Co. Ltd. made no entries, exports, or sales of the subject merchandise during the POR covered by this administrative review. Consequently, these companies' separate rates remain unchanged from the last administrative review.

China-Wide Entity

For the purposes of the final results of this administrative review, we continue to find that the following entities are part of the China-wide entity because they failed to submit both a response to Commerce's quantity and value questionnaire and information to establish eligibility for a separate rate: (1) Activa International Inc.; (2) Atlas Integrated Manufacturing Ltd.; (3) Belton (Asia) Development Ltd.; (4) Belton (Asia) Development Limited; (5) Changzhou Tenglong Auto Parts Co., Ltd.; (6) Changzhou Tenglong Auto Accessories Manufacturing Co. Ltd.; (7) Changzhou Tenglong Auto Parts Co Ltd; (8) China Square; (9) China Square Industrial Co.; (10) China Square Industrial Ltd; (11) Daya Hardware Co Ltd; (12) ETLA Technology (Wuxi) Co. Ltd; (13) Global Hi-Tek Precision Co. Ltd; (14) Guangdong Whirlpool Electrical Appliances Co., Ltd.; (15) Guangdong Zhongya Aluminium Company Limited; (16) Henan New Kelong Electrical Appliances Co., Ltd.;

⁸ Initially, this administrative review covered 220 companies. See *Initiation Notice*, 82 FR at 31294. However, Commerce rescinded this administrative review with respect to 191 companies for which all review requests were timely withdrawn. See *Preliminary Results*, 83 FR at 5604, and accompanying Preliminary Decision Memorandum.

⁹ See *Aluminum Extrusions from the People's Republic of China: Antidumping Duty Order*, 76 FR 30650 (May 26, 2011) (the Order).

¹⁰ For a complete description of the scope of the Order, see Memorandum, "Issues and Decisions Memorandum for the Final Results of the Antidumping Duty Administrative Review: Aluminum Extrusions from the People's Republic of China; 2016–2017," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

¹¹ See the Order.

¹² See Issues and Decision Memorandum, at Comment 2.

(17) Liaoning Zhongwang Group Co., Ltd.; (18) Liaoyang Zhongwang Aluminum Profile Co. Ltd.; (19) Midea International Training Co., Ltd.; (20) Midea International Trading Co., Ltd.; (21) Shenyang Yuanda Aluminum Industry Engineering Co. Ltd.; (22) Sincere Profit Limited; (23) Summit Heat Sinks Metal Co, Ltd; (24) USA Worldwide Door Components (PINGHU) Co., Ltd.; (25) Whirlpool Canada L.P.; and (26) Whirlpool Microwave Products Development Ltd.¹³

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.¹⁴ Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity in the instant review, the entity is not under review, and the entity's current rate, *i.e.*, 86.01 percent,¹⁵ is not subject to change.

Adjustments for Countervailable Subsidies

Because no company established eligibility for an adjustment under section 777A(f) of the Act for countervailable domestic subsidies, for these final results, Commerce did not make an adjustment pursuant to section 777A(f) of the Act for countervailable domestic subsidies for separate-rate recipients. Furthermore, because the China-wide entity is not under review, we made no adjustment for countervailable export subsidies for the China-wide entity pursuant to section 772(c)(1)(C) of the Act.

Assessment

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review in the **Federal Register**. Consistent with Commerce's assessment practice in non-market economy (NME) cases, if Commerce determines that an exporter under

review had no shipments of subject merchandise, any suspended entries that entered under the exporter's case number (*i.e.*, at that exporter's rate) will be liquidated at the China-wide rate.¹⁶

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed Chinese and non-Chinese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the exporter-specific rate published for the most-recently completed segment of this proceeding in which the exporter was reviewed; (2) for all Chinese exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be that established for the China-wide entity, which is 86.01 percent; and (3) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter with the subject merchandise. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance

with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing notice of these final results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and sections 351.213(h) and 351.221(b)(5) of Commerce's regulations.

Dated: July 23, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Discussion of the Issues
 - Comment 1: Adjustment of Liquidation Instructions
 - Comment 2: Xin Wei/Regal Separate Rate
5. Recommendation

[FR Doc. 2018–16071 Filed 7–26–18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2015–2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) continues to find that manufacturers/exporters of crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells) sold solar products at less than normal value during the period of review (POR), December 1, 2015, through November 30, 2016.

DATES: Applicable July 27, 2018.

FOR FURTHER INFORMATION CONTACT: Jeff Pedersen and Krisha Hill, AD/CVD

¹³ See *Preliminary Results*, 83 FR at 5606.

¹⁴ See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963, 65970 (November 4, 2013).

¹⁵ See *Aluminum Extrusions from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2015–2016*, 82 FR 52265, 52267 (November 13, 2017).

¹⁶ See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011).

Operations, Office IV, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-2769 and (202) 482-4037.

SUPPLEMENTARY INFORMATION:

Background

On January 9, 2018, Commerce published in the **Federal Register** the preliminary results of the 2015–2016 administrative review of the antidumping duty order on solar cells from the People's Republic of China (China).¹ For events subsequent to the *Preliminary Results*, see Commerce's Issues and Decision Memorandum.² The final weighted-average dumping margins are listed below in the "Final Results of Review" section of this notice.

Commerce has exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from January 20 through 22, 2018.³ On May 8, 2018, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), Commerce extended the deadline for issuing the final results by 60 days,⁴ postponing the final results until July 11, 2018.

Scope of the Order

The merchandise covered by this order is crystalline silicon photovoltaic cells and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials.⁵ Merchandise covered by this order is currently

classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 8501.61.0000, 8507.20.80, 8541.40.6020, 8541.40.6030, and 8501.31.8000. Although these HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs filed by parties in this review are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, follows as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov> and to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at <http://enforcement.trade.gov/frn/>. The paper copy and electronic version of the Issues and Decision Memorandum are identical in content.

Affiliation and Single Entity Determination

We preliminarily found that Changzhou Trina Solar Energy Co., Ltd./Trina Solar (Changzhou) Science and Technology Co., Ltd./Yancheng Trina Solar Energy Technology Co., Ltd./Changzhou Trina Solar Yabang Energy Co., Ltd./Turpan Trina Solar Energy Co., Ltd./Hubei Trina Solar Energy Co., Ltd. are affiliated with Trina Solar (Hefei) Science and Technology Co., Ltd., pursuant to section 771(33)(F) of the Act and that all of these companies should be treated as a single entity, *i.e.*, Trina Solar (Hefei) Science and Technology Co., Ltd. (Trina), pursuant to 19 CFR 351.401(f)(1)–(2).⁶ No interested party has disputed this treatment, and so these findings remain unchanged for these final results.

Changes Since the Preliminary Results⁷

Based on a review of the record and comments received from interested parties regarding our *Preliminary*

Results, and for the reasons explained in the Issues and Decision Memorandum, we made revisions to our preliminary calculations of the weighted-average dumping margin for the mandatory respondent Trina.

Final Determination of No Shipments

In the *Preliminary Results*, we found that the following eight companies had no shipments during the POR: De-Tech Trading Limited HK, Dongguan Sunworth Solar Energy Co., Ltd., Jiawei Solarchina Co., Ltd., Ningbo ETDZ Holdings, Ltd., Shenzhen Sungold Solar Co., Ltd., Taizhou BD Trade Co., Ltd., Toenergy Technology Hangzhou Co., Ltd., and Wuxi Tianran Photovoltaic Co., Ltd.⁸ We did not receive comments from interested parties regarding our preliminary finding on no shipments. Consistent with Commerce's assessment practice in non-market economy cases, we completed the review with respect to the above-named companies. Based on the certifications submitted by the aforementioned companies, and our analysis of Customs and Border Protection (CBP) information,⁹ we continue to determine that these companies did not have any reviewable transactions during the POR. As noted in the "Assessment" section below, Commerce will issue appropriate instructions with respect to these companies to CBP based on our Final Results.¹⁰ In addition, these companies will maintain their rate from the most recent segment in which they participated.

Separate Rates

In the *Preliminary Results*, we found that evidence provided by Trina and 21 other companies/company groups supported finding an absence of both de jure and de facto government control, and, therefore, we preliminarily granted a separate rate to each of these companies/company groups.¹¹ We received no information since the issuance of the *Preliminary Results* that provides a basis for reconsidering these determinations with respect to the separate rate status of these 22 companies/company groups. Therefore, for the final results, we continue to find that these entities are eligible for separate rates.

¹ See *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2015–2016*, 83 FR 1018 (January 9, 2018) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Issues and Decision Memorandum for the Final Results of the 2015–2016 Antidumping Duty Administrative Review of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, From the People's Republic of China," (Issues and Decision Memorandum), dated concurrently with this notice.

³ See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated January 23, 2018 (Tolling Memorandum). All deadlines in this segment of the proceeding have been extended by three days.

⁴ See Memorandum, "2015–2016 Antidumping Duty Administrative Review of Certain Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review," dated May 8, 2018.

⁵ For a complete description of the scope of the order, see Issues and Decision Memorandum.

⁶ See *Preliminary Results* and accompanying PDM at 6.

⁷ See Issues and Decision Memorandum at comments 2 and 10.

⁸ See *Preliminary Results*, 83 FR 1018.

⁹ See PDM at 4–5.

¹⁰ See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011) (Assessment of Antidumping Duties); see also the "Assessment" section of this notice, below.

¹¹ See *Preliminary Results*, 83 FR 1018; see also PDM at 11–12.

Final Results of Review

We determine that the following weighted-average dumping margins exist for the POR:

Exporter	Weighted-average dumping margin (percent)
Changzhou Trina Solar Energy Co., Ltd./Trina Solar (Changzhou) Science and Technology Co., Ltd./Yancheng Trina Solar Energy Technology Co., Ltd./Changzhou Trina Solar Yabang Energy Co., Ltd./Turpan Trina Solar Energy Co., Ltd./Hubei Trina Solar Energy Co., Ltd./Trina Solar (Hefei) Science and Technology Co., Ltd	15.85
Anji DaSol Solar Energy Science & Technology Co., Ltd	15.85
Chint Solar (Zhejiang) Co., Ltd	15.85
ET Solar Energy Limited	15.85
Hangzhou Sunny Energy Science and Technology Co., Ltd	15.85
Hengdian Group DMEGC Magnetics Co. Ltd	15.85
JA Solar Technology Yangzhou Co., Ltd	15.85
Jiawei Solarchina (Shenzhen) Co., Ltd	15.85
JingAo Solar Co., Ltd	15.85
LERRI Solar Technology Co., Ltd. (aka LONGi Solar Technology Co. Ltd.)	15.85
Lightway Green New Energy Co., Ltd	15.85
Ningbo Qixin Solar Electrical Appliance Co., Ltd	15.85
Risen Energy Co., Ltd	15.85
Shanghai JA Solar Technology Co., Ltd	15.85
Shenzhen Topray Solar Co., Ltd	15.85
Sumec Hardware & Tools Co., Ltd	15.85
Sunpreme Jiaying Ltd	15.85
tenKsolar (Shanghai) Co., Ltd	15.85
Wuxi Suntech Power Co., Ltd/Luoyang Suntech Power Co., Ltd	15.85
Yingli Energy (China) Company Limited/Baoding Tianwei Yingli New Energy Resources Co., Ltd./Tianjin Yingli New Energy Resources Co., Ltd./Hengshui Yingli New Energy Resources Co., Ltd./Lixian Yingli New Energy Resources Co., Ltd./Baoding Jiasheng Photovoltaic Technology Co., Ltd./Beijing Tianneng Yingli New Energy Resources Co., Ltd./Hainan Yingli New Energy Resources Co., Ltd	15.85
Zhejiang ERA Solar Technology Co., Ltd	15.85
Zhejiang Sunflower Light Energy Science & Technology Limited Liability Company	15.85

Commerce's change in policy regarding conditional review of the China-wide entity applies to this administrative review.¹² Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity, we did not conduct a review of the China-wide entity. Thus, the weighted-average dumping margin for the China-wide entity (*i.e.*, 238.95 percent) is not subject to change as a result of this review.¹³

Assessment

Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. Commerce intends to issue

assessment instructions to CBP 15 days after the publication date of these Final Results of review. In accordance with 19 CFR 351.212(b)(1), we are calculating importer- (or customer)-specific assessment rates for the merchandise subject to this review. For any individually examined respondent whose weighted-average dumping margin is above *de minimis* (*i.e.*, 0.50 percent), Commerce will calculate importer- (or customer)-specific assessment rates for merchandise subject to this review. Where the respondent reported reliable entered values, Commerce calculated importer- (or customer)-specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to the importer (or customer) and dividing this amount by the total entered value of the sales to the importer (or customer).¹⁴ Where Commerce calculated an importer- (or customer)-specific weighted-average dumping margin by dividing the total amount of dumping for reviewed sales to the importer (or customer) by the total sales quantity associated with those transactions,

Commerce will direct CBP to assess importer- (or customer)-specific assessment rates based on the resulting per-unit rates.¹⁵ Where an importer- (or customer)-specific *ad valorem* or per-unit rate is greater than *de minimis*, Commerce will instruct CBP to collect the appropriate duties at the time of liquidation. Where either the respondent's weighted average dumping margin is zero or *de minimis*, or an importer- (or customer)-specific *ad valorem* or per-unit rate is zero or *de minimis*, Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.¹⁶

For merchandise whose sale/entry was not reported in the U.S. sales database submitted by an exporter individually examined during this review, but that entered under the case number of that exporter (*i.e.*, at the individually-examined exporter's cash deposit rate), Commerce will instruct CBP to liquidate such entries at the

¹² See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963, 65969–70 (November 4, 2013).

¹³ See *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2014–2015*, 82 FR 29033 (June 27, 2017).

¹⁴ See 19 CFR 351.212(b)(1).

¹⁵ *Id.*

¹⁶ See *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification*, 77 FR 8101, 8103 (February 14, 2012).

China-wide rate. Additionally, if Commerce determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number will be liquidated at the China-wide rate.¹⁷

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the Final Results of this administrative review for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register**, as provided by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be the rate listed for each exporter in the table in the "Final Results of Review" section of this notice, except if the rate is zero or *de minimis* (i.e., less than 0.5 percent), then the cash deposit rate will be zero; (2) for previously investigated Chinese and non-Chinese exporters that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate previously established for the PRC-wide entity (i.e., 238.95 percent); and (4) for all non-China exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied the non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed for these Final Results within five days of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties

occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: July 11, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—Issues and Decision Memorandum

Summary

Background

Scope of the Order

Discussion of the Issues

Comment 1. Whether Commerce Should Apply Partial Adverse Facts Available to Trina's Unreported Factors of Production for Purchased Solar Cells

Comment 2. Ministerial Error Allegations

Comment 3. Whether Commerce Should Adjust the U.S. Price for "USDUTYU" Expenses

Comment 4. Whether Commerce Should Include Trina's Sale to a Salvage Company in the Margin Calculation

Comment 5. Whether Commerce Should Adjust U.S. Price for the Export Buyer's Credits Program

Comment 6. Zero-Quantity Import Data

Comment 7. Surrogate Value for Aluminum Frames

Comment 8. Surrogate Value for International Freight

Comment 9. Surrogate Value for Nitrogen

Comment 10. Selection of Surrogate Financial Statements

Comment 11. Surrogate Value for Labor

Comment 12. Separate Rate Status for LONGi Solar Technology Co. Ltd.

Comment 13. Differential Pricing

Recommendation

[FR Doc. 2018-16072 Filed 7-26-18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-533-869]

Certain New Pneumatic Off-the-Road Tires From India: Notice of Rescission of Antidumping Duty Administrative Review; 2017-2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the antidumping duty (AD) order on certain new pneumatic off-the-road tires (OTR Tires) from India for the period of review (POR) February 2, 2017, through February 28, 2018.

DATES: Applicable July 27, 2018.

FOR FURTHER INFORMATION CONTACT: Trisha Tran, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-4852.

SUPPLEMENTARY INFORMATION:

Background

On March 5, 2018, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the AD order on OTR Tires from India for the period February 2, 2017, through February 28, 2018.¹ On March 30, 2018, ATC Tires Private Limited (ATC) and Alliance Tires Americas, Inc. (ATA) (collectively ATC) timely requested that Commerce conduct an administrative review of this AD order with respect to ATC.² No other party requested a review of the order. On May 2, 2018, Commerce initiated an administrative review with respect to ATC, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.221(c)(1)(i).³ On May 17, 2018, ATC timely withdrew its request for an administrative review.⁴ No other party requested a review of ATC.

¹ See *Antidumping or Countervailing Duty, Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review*, 83 FR 9284 (March 5, 2018).

² See Letter from ATC, "Certain New Pneumatic Off-the-Road Tires from India: ATC Tires Private Limited's Request for Administrative Review," dated March 30, 2018.

³ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 83 FR 19215 (May 2, 2018).

⁴ See Letter from ATC, "Certain New Pneumatic Off-the-Road Tires from India: ATC Tires Private Limited's Withdrawal of Request for Administrative Review," dated May 17, 2018.

¹⁷ See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011), for a full discussion of this practice.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested a review withdraws the request within 90 days of the publication date of the notice of initiation of the requested review. In this case, ATC timely withdrew its request for review within 90 days of the publication date of the *Initiation Notice*. Because Commerce received no other request for a review of the AD order with respect to ATC, and no other requests were made for a review of the AD order with respect to other companies, we are rescinding this administrative review covering the period February 2, 2017, through February 28, 2018, in its entirety, in accordance with 19 CFR 213(d)(1).

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of OTR Tires from India during the POR. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the publication of this notice in the **Federal Register**.

Notification to Importers

This notice also serves as a final reminder to importers for whom this review is being rescinded of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to

judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: July 23, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–16074 Filed 7–26–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Notice of Partial Rescission of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable July 27, 2018.

FOR FURTHER INFORMATION CONTACT: Krisha Hill, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4037.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2012, the Department of Commerce (Commerce) published in the **Federal Register** the antidumping duty order on crystalline silicon photovoltaic cells, whether or not assembled into modules, from the People's Republic of China (China) (Order).¹ On December 4, 2017, Commerce published a notice of opportunity to request an administrative review of the Order.² Commerce received multiple timely requests for an administrative review of the Order. On February 23, 2018, in accordance with

¹ See *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order*, 77 FR 73018 (December 7, 2012).

² See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 82 FR 57219 (December 4, 2017).

section 751(a) of Tariff Act of 1930, as amended (the Act), Commerce published in the **Federal Register** a notice of the initiation of an administrative review of the Order.³ The administrative review was initiated with respect to 45 companies or groups of companies, and covers the period from December 1, 2016, through November 30, 2017. All parties have subsequently timely withdrawn their requests to review the group Changzhou Trina Solar Energy Co., Ltd./Trina Solar (Changzhou) Science and Technology Co., Ltd./Yancheng Trina Solar Energy Technology Co., Ltd./Changzhou Trina Solar Yabang Energy Co., Ltd./Turpan Trina Solar Energy Co., Ltd./Hubei Trina Solar Energy Co., Ltd. (collectively, Trina).⁴

Rescission of Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the date of publication of the notice of initiation of the requested review. All parties withdrew their requests for an administrative review of Trina within 90 days of the date of publication of the *Initiation Notice*. Accordingly, Commerce is rescinding this review with respect to Trina, in accordance with 19 CFR 351.213(d)(1).

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all subject merchandise exported by Trina and entered, or withdrawn from warehouse, for consumption during the period of review at a rate equal to the cash deposit of estimated antidumping duties required at the time of entry in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice in the **Federal Register**.

³ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 83 FR 8058 (February 23, 2018) (*Initiation Notice*).

⁴ See Letter from SolarWorld Americas, Inc., “Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Withdrawal of Request for Administrative Review and Request for Selection of Additional Mandatory Respondent,” dated April 5, 2018; see also Letter from Changzhou Trina Solar Energy Co., Ltd., Yancheng Trina Solar Energy Technology Co., Ltd., and Changzhou Trina Solar Yabang Energy Co., Ltd., “Crystalline Silicon Photovoltaic Cells, Whether Or Not Assembled into Modules from the People's Republic of China—Withdrawal of Request for Review,” dated April 4, 2018.

Notification to Importers

This notice serves as the only reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: July 23, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018-16073 Filed 7-26-18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648-XG320

Marine Mammals; File No. 21678

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that John Calambokidis, Cascadia Research Collective, Waterstreet Building Suite 201, 218½ West Fourth Ave., Olympia, WA 98501, has applied in due form for a permit to conduct research on marine mammals.

DATES: Written, telefaxed, or email comments must be received on or before August 27, 2018.

ADDRESSES: The application and related documents are available for review by selecting "Records Open for Public Comment" from the "Features" box on the Applications and Permits for Protected Species (APPS) home page, <https://apps.nmfs.noaa.gov>, and then selecting File No. 21678 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427-8401; fax (301) 713-0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713-0376, or by email to NMFS.Pr1Comments@noaa.gov. Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Carrie Hubbard or Sara Young, (301) 427-8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222-226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The applicant proposes to continue long-term studies of marine mammals in the eastern North Pacific. Research would be conducted primarily along the west coast of the United States from the Mexico border to Canada, but may also occur in Alaskan waters and international waters of the Pacific Ocean. Twenty-four cetacean species would be studied, including those listed as endangered or threatened: Blue (*Balaenoptera musculus*), fin (*B. physalus*), humpback (*Megaptera novaeangliae*), Eastern North Pacific Southern Resident killer (*Orcinus orca*),

North Pacific right (*Eubalaena japonica*), sei (*B. borealis*), and sperm (*Physeter macrocephalus*) whales. Research methods vary by species, but would include vessel surveys, aerial surveys, unmanned aircraft systems (UAS), photo-identification, behavioral observations, passive acoustic recordings, underwater photography, sampling (breath, skin, feces, skin/blubber), prey mapping, and suction cup and dart tagging. Five species of pinnipeds, including Steller sea lions (*Eumetopias jubatus*) would also be studied, primarily at haul out areas in Puget Sound, WA. Seals and sea lions may be disturbed during abundance counts, scat collection, and UAS flights. The research would examine population size and trends, habitat use, social structure, range, movement patterns and rates, diving behavior, diet, ecology, behavior and the impacts of human activities on marine mammals. The permit would be valid for five years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: July 24, 2018.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018-16057 Filed 7-26-18; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED**Procurement List; Proposed Addition and Deletions**

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Notice; correction.

SUMMARY: The Committee for Purchase From People Who Are Blind or Severely Disabled published a document in the **Federal Register** of July 20, 2018, concerning a notice of Proposed Addition and Deletions.

FOR FURTHER INFORMATION CONTACT: For further information or to submit

comments contact: Michael R. Jurkowski, Telephone: (703) 603-2117.

Correction

In the **Federal Register** of July 20, 2018, in FR Doc. 2018-15571 (83 FR 140), the Committee would like to correct the notice for "Procurement List, Proposed Addition and Deletions" to replace the Initial Regulatory Flexibility Act Certification:

Procurement List; Proposed Addition to and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Addition to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add a service to the Procurement List that will be furnished by a nonprofit agency employing persons who are blind or have other severe disabilities, and deletes products and services previously furnished by such agencies.

DATES: Comments must be received on or before: August 19, 2018.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202-4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 603-2117, Fax: (703) 603-0655, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Addition

If the Committee approves the proposed addition, the entities of the Federal Government identified in this notice will be required to procure the service listed below from the nonprofit agency employing persons who are blind or have other severe disabilities.

The following service is proposed for addition to the Procurement List for production by the nonprofit agency listed:

Service

Service Type: Document Destruction Service
Mandatory for: Defense Logistics Agency, Defense Supply Center, 3990 East Broad Street, Columbus, OH

Mandatory Source(s) of Supply: Greene, Inc., Xenia, OH

Contracting Activity: Defense Logistics Agency Contracting SVCS OFF, Columbus

Deletions

The following products and services are proposed for deletion from the Procurement List:

Products

NSN(s)—Product Name(s):

6230-01-617-3776—Kit, Safety Flare, Programmable Flicker Pattern, Red LED, 8in Diameter, AA Battery Operated
6230-01-617-6959—Kit, Safety Flare, Programmable Flicker Pattern, Red LED, 8in Diameter, Rechargeable Power Unit

Mandatory Source(s) of Supply: Tarrant County Association for the Blind, Fort Worth, TX

Contracting Activity: Defense Logistics Agency Troop Support

NSN(s)—Product Name(s):

6545-07-000-0762—USMC Individual First Aid Kit, Complete

6545-09-000-2727—Minor First Aid Kit, USMC Individual First Aid Kit

Mandatory Source(s) of Supply: Chautauqua County Chapter, NYSARC, Jamestown, NY

Contracting Activity: Commander, Quantico, VA

NSN(s)—Product Name(s):

8415-01-502-3285—Silk/Lightweight Drawers, Size Small—Regular, Green
8415-01-502-3287—Silk/Lightweight Drawers, Size Medium—Regular, Green
8415-01-502-3288—Silk/Lightweight Drawers, Size Large—Regular, Green
8415-01-502-3289—Silk/Lightweight Drawers, Size Large—Long, Green
8415-01-502-3290—Silk/Lightweight Drawers, Size Extra Large—Regular
8415-01-502-3292—Silk/Lightweight Drawers, Size Extra Large—Long, G
8415-01-502-3321—Green, Midweight Undershirt, Size Short—Regular
8415-01-502-3322—Green, Midweight Undershirt, Size Medium—Regular
8415-01-502-3324—Green, Midweight Undershirt, Size Large—Regular
8415-01-502-3325—Green, Midweight Undershirt, Extra Large—Regular
8415-01-502-3328—Green, Midweight Undershirt, Large—Long
8415-01-502-3341—Green, Midweight Undershirt, X-Large—Long
8415-01-502-4366—Silk/Lightweight Undershirts, Size Small—Regular,
8415-01-502-4368—Silk/Lightweight Undershirts, Size Medium—Regular,
8415-01-502-4370—Silk/Lightweight Undershirts, Size Large—Regular,
8415-01-502-4371—Silk/Lightweight Undershirts, Size Large—Long, Green
8415-01-502-4373—Silk/Lightweight Undershirts, Size Extra Large—Reg
8415-01-502-4375—Silk/Lightweight Undershirts, Size Extra Large—Long

Mandatory Source(s) of Supply: Peckham Vocational Industries, Inc., Lansing, MI, Southeastern Kentucky Rehabilitation Industries, Inc., Corbin, KY

Contracting Activity: Defense Logistics Agency Troop Support

NSN(s)—Product Name(s):

5340-01-230-0219—Bracket, Angle with Four Holes, Abrams M-1 Tank, Green

5340-01-386-2917—Bracket, Angle, Command AAVC-7A1 Amphibious Assault Vehicle

5340-01-112-9693—Bracket, Angle, Bradley Fighting Vehicle System

5340-01-525-0579—Bracket, Angle, Right Side, Medium Tactical Vehicles

5340-01-102-3483—Bracket, Angle with Two Holes, Abrams M-1 Tank

5340-01-525-0574—Bracket, Angle, Left Side, Medium Tactical Vehicles

5340-01-519-7318—Bracket, Angle, Truck 1¼ Ton HMMWV Vehicle System

5340-01-162-7040—Bracket, Angle, Personnel M113A1, M113-A2, M-113A3 Armored Carrier

5340-01-163-4245—Bracket, Double Angle, Hercules M88A2 Recovery Vehicle

5340-01-288-5231—Bracket, Double Angle, Bradley Fighting Vehicle System

5340-01-167-1810—Bracket, Mounting, Personnel M113A1, M113-A2, M-113A3 Armored Carrier

5340-01-329-8589—Bracket, Mounting, Bradley Fighting Vehicle System

5340-01-084-1232—Bracket, Mounting, Cargo Truck

5340-01-500-4197—Bracket, Mounting, Mine Resistant Ambush Protected Fighting Vehicle

5340-00-627-5411—Bracket, Mounting, Stratofortress B-52 Aircraft

5340-01-347-9608—Bracket, Mounting, F-16 Aircraft

5340-00-602-4977—Bracket, Mounting, Hercules M88A2 Recovery Vehicle

5340-01-272-6634—Bracket, Mounting, Truck 1¼ Ton HMMWV Vehicle System

5340-01-098-5119—Bracket, Mounting, Howitzer M-109

5340-01-078-7642—Bracket, Mounting, Abrams M-1 Tank

5340-01-521-0196—Bracket, Mounting, Non-Weapons System

5340-01-458-0473—Bracket, Mounting, M-16 Rifle 5.56MM

Mandatory Source(s) of Supply: Unknown

Contracting Activity: Defense Logistics Agency Troop Support

NSN(s)—Product Name(s):

6840-00-NIB-0039—Disinfectant Spray, Aerosol, Lysol Brand III, Original Scent
6840-00-NIB-0040—Disinfectant Spray, Aerosol, Lysol Brand III, Fresh Scent
6840-00-NIB-0041—Disinfectant Spray, Aerosol, Lysol Brand III, Country Scent
6840-00-NIB-0042—Disinfectant Spray, Aerosol, Lysol Brand III, Crisp Linen Scent

6840-00-NIB-0043—Disinfectant Spray, Aerosol, Lysol Brand III, Spring Waterfall Scent

Mandatory Source(s) of Supply: LC Industries, Inc., Durham, NC

Contracting Activity: General Services Administration, New York, NY

Services

Service Type: Janitorial/Custodial Service

Mandatory for: USPS, Mail Transportation Equipment Center: 7600 West Roosevelt Road, Forest Park, IL

Mandatory Source(s) of Supply: Lester and Rosalie ANIXTER CENTER, Chicago, IL

Contracting Activity: U.S. Postal Service,

Washington, DC
Service Type: Janitorial/Custodial Service
Mandatory for: Naval Air Reserve Center,
 6201 32nd Avenue, Minneapolis, MN
Mandatory Source(s) of Supply:
 AccessAbility, Inc., Minneapolis, MN
Contracting Activity: Dept of the Navy, U.S.
 Fleet Forces Command
Service Type: Laundry Service
Mandatory for: U.S. Army Aviation Support
 Command: CMPSC Commissary, Granite
 City, IL
Mandatory Source(s) of Supply: Unknown
Contracting Activity: Dept of the Army,
 W40M Northregion Contract Ofc

Dated: July 24, 2018.

Michael R. Jurkowski,
*Business Management Specialist, Business
 Operations.*

[FR Doc. 2018-16105 Filed 7-26-18; 8:45 am]

BILLING CODE 6353-01-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From
People Who Are Blind or Severely
Disabled.

ACTION: Additions to the Procurement
List.

SUMMARY: This action adds services to
the Procurement List that will be
provided by nonprofit agencies
employing persons who are blind or
have other severe disabilities.

DATES: *Date added to the Procurement
List:* August 26, 2018.

ADDRESSES: Committee for Purchase
From People Who Are Blind or Severely
Disabled, 1401 S Clark Street, Suite 715,
Arlington, Virginia 22202-4149.

FOR FURTHER INFORMATION CONTACT:
Michael R. Jurkowski, Telephone: (703)
603-2117, Fax: (703) 603-0655, or email
CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION:

Additions

On 5/18/2018 (83 FR 97) and 6/15/
2018 (83 FR 116), the Committee for
Purchase From People Who Are Blind
or Severely Disabled published notices
of proposed additions to the
Procurement List.

After consideration of the material
presented to it concerning capability of
qualified nonprofit agencies to provide
the services and impact of the additions
on the current or most recent
contractors, the Committee has
determined that the services listed
below are suitable for procurement by
the Federal Government under 41 U.S.C.
8501-8506 and 41 CFR 51-2.4.

Regulatory Flexibility Act Certification

I certify that the following action will
not have a significant impact on a
substantial number of small entities.
The major factors considered for this
certification were:

1. The action will not result in any
additional reporting, recordkeeping or
other compliance requirements for small
entities other than the small
organizations that will provide the
services to the Government.

2. The action will result in
authorizing small entities to provide the
services to the Government.

3. There are no known regulatory
alternatives which would accomplish
the objectives of the Javits-Wagner-
O'Day Act (41 U.S.C. 8501-8506) in
connection with services proposed for
addition to the Procurement List.

End of Certification

Accordingly, the following services
are added to the Procurement List:

Services

Service Type: Recycling Service
Mandatory for: U.S. Army, Walter Reed
 Army Institute of Research, Safety &
 Environment Department, Forest Glen
 Annex, Buildings 500, 501, 503, 508,
 509, 511 & the Temporary Phasing
 Facilities, 503 Robert Grant Avenue,
 Silver Spring, MD
Mandatory Source(s) of Supply: MVLE, Inc.,
 Springfield, VA
Contracting Activity: Dept Of The Army,
 W4PZ USA MED RSCH ACQUIS ACT
Service Type: Facilities Operation and
 Maintenance Service
Mandatory for: National Institutes of Health,
 NIH Animal Center, 16701 Elmer School
 Road, Dickerson, MD
Mandatory Source(s) of Supply: Skookum
 Educational Programs, Bremerton, WA
Contracting Activity: National Institutes of
 Health, NIH A E Construction

Michael R. Jurkowski,
*Business Management Specialist, Business
 Operations.*

[FR Doc. 2018-16106 Filed 7-26-18; 8:45 am]

BILLING CODE 6353-01-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Addition and Deletions

AGENCY: Committee for Purchase From
People Who Are Blind or Severely
Disabled.

ACTION: Proposed addition to and
deletions from the Procurement List.

SUMMARY: The Committee is proposing
to add a service to the Procurement List
that will be provided by the nonprofit

agency employing persons who are
blind or have other severe disabilities,
and deletes a product and service
previously furnished by such agencies.

DATES: *Comments must be received on
or before:* August 26, 2018.

ADDRESSES: Committee for Purchase
From People Who Are Blind or Severely
Disabled, 1401 S. Clark Street, Suite
715, Arlington, Virginia 22202-4149.

FOR FURTHER INFORMATION CONTACT: For
further information or to submit
comments contact: Michael R.
Jurkowski, Telephone: (703) 603-2117,
Fax: (703) 603-0655, or email
CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: This
notice is published pursuant to 41
U.S.C. 8503(a)(2) and 41 CFR 51-2.3. Its
purpose is to provide interested persons
an opportunity to submit comments on
the proposed actions.

Addition

If the Committee approves the
proposed addition, the entities of the
Federal Government identified in this
notice will be required to procure the
service listed below from the nonprofit
agency employing persons who are
blind or have other severe disabilities.

The following service is proposed for
addition to the Procurement List for
production by the nonprofit agency
listed:

Service

Service Type: Grounds Maintenance Service
Mandatory for: U.S. Air Force, Cannon Air
 Force Base, 110 Alison Avenue, Cannon
 AFB, NM
Mandatory Source(s) of Supply: CW
 Resources, Inc., New Britain, CT
Contracting Activity: Dept of the Air Force,
 FA4855 27 SOCONS LGC

Deletions

The following product and service are
proposed for deletion from the
Procurement List:

Product

NSN(s)—Product Name(s): 8410-00-NSH-
 6369—Knee Length, X Large
Mandatory Source(s) of Supply: Human
 Technologies Corporation, Utica, NY
Contracting Activity: AMS 31C3,
 Washington, DC

Service

Service Type: Ground Maintenance Service
Mandatory for: Niagara Falls International
 Airport: 914th Tactical Airlift Group
 (AFRES), Niagara Falls, NY
Mandatory Source(s) of Supply: Unknown
Contracting Activity: DEPT of the Air Force,

FA7014 AFDW PK

Michael R. Jurkowski,
Business Management Specialist, Business
Operations.

[FR Doc. 2018-16109 Filed 7-26-18; 8:45 am]

BILLING CODE 6353-01-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Charter Renewal of Department of Defense Federal Advisory Committees

AGENCY: Department of Defense.

ACTION: Renewal of Federal Advisory Committee.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that it is renewing the charter for the Army Education Advisory Committee ("the Committee").

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703-692-5952.

SUPPLEMENTARY INFORMATION: The Committee's charter is being renewed in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended) and 41 CFR 102-3.50(d). The Committee's charter and contact information for the Committee's Designated Federal Officer (DFO) can be found at <http://www.facadatabase.gov/>.

The Committee provides the Secretary of Defense and the Deputy Secretary of Defense, through the Secretary of the Army, independent advice and recommendations on Army educational matters, pertaining to the educational doctrinal, and research policies and activities of the U.S. Army's educational programs, to include the U.S. Army's joint professional military education programs. The committee will access and provide independent advice and recommendations across the spectrum of educational policies, school curricula, educational philosophy and objectives, program effectiveness, facilities, staff and faculty, instructional methods, and other aspects of the organization and management of these programs. In addition, the Committee will provide independent advice and recommendations on matters pertaining to the Army Historical Program and the role and mission of the U.S. Army Center of Military History, particularly as they pertain to the study and use of military history in Army schools.

The Committee is composed of no more than 15 members and will include the following: a. Not more than 13

individuals who are eminent authorities in the fields of defense, management, leadership, and academia, including those who are deemed to be historical scholars; b. the Chief Historian of the Army, U.S. Army, Center of Military History; and c. the Assistant Deputy Chief of Staff, G-3/5/7 for U.S. Army Training and Doctrine Command, who will serve as a non-voting member of the Committee. All members of the Committee are appointed to provide advice on behalf of the Government on the basis of their best judgment without representing any particular point of view and in a manner that is free from conflict of interest. Except for reimbursement of official Committee-related travel and per diem, Committee members serve without compensation.

The public or interested organizations may submit written statements to the Committee membership about the Committee's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Committee. All written statements shall be submitted to the DFO for the Committee, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: July 24, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison
Officer, Department of Defense.

[FR Doc. 2018-16049 Filed 7-26-18; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD-2018-OS-0027]

Submission for OMB Review; Comment Request

AGENCY: Defense Security Service, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by August 27, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Sehra, DoD Desk Officer, at oir_submission@omb.eop.gov. Please identify the proposed information collection by DoD

Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571-372-0493, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Certificate Pertaining to Foreign Interest; SF328; OMB Control Number 0704-XXXX.

Type of Request: New.

Number of Respondents: 2,123.

Responses per Respondent: 1.

Annual Responses: 2,123.

Average Burden per Response: 70 minutes.

Annual Burden Hours: 2,476.8.

Needs and Uses: Completion of the SF 328 (which will be designated as a Common Form allowing its use by other federal agencies) and submission of supporting documentation (e.g., company or entity charter documents, board meeting minutes, stock or securities information, descriptions of organizational structures, contracts, sales, leases and/or loan agreements and revenue documents, annual reports and income statements, etc.) is part of the eligibility determination for access to classified information and/or issuance of a Facility Clearance.

Affected Public: Business or Other For-Profit; Not-For-Profit Institutions.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Sehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: July 23, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison
Officer, Department of Defense.

[FR Doc. 2018-16034 Filed 7-26-18; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD-2018-OS-0025]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by August 27, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Sehra, DoD Desk Officer, at oira_submission@omb.eop.gov. Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571-372-0493, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Data for Payment of Retired Personnel; DD Form 2656; OMB Control Number 0704-0569.

Type of Request: Revision.

Number of Respondents: 66,800.

Responses per Respondent: 1.

Annual Responses: 66,800.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 16,700.

Needs and Uses: The information collection requirement is necessary to obtain applicable retirement information from Uniformed Service members and allow those members to make certain retired pay and survivor annuity elections prior to retirement from service or prior to reaching eligibility to receive retired pay. The form will also allow eligible members covered by the Blended Retirement System to make a voluntary election of a partial lump sum of retired pay, as required by Section 1415 of title 10, United States Code.

Affected Public: Individuals or Households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Sehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: July 23, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison
Officer, Department of Defense.

[FR Doc. 2018-16033 Filed 7-26-18; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD-2015-OS-0054]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by August 27, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Sehra, DoD Desk Officer, at oira_submission@omb.eop.gov. Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571-372-0493, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application for Surrogate Association for DoD Self-Service (DS) Logon; DD Form x683; OMB Control Number 0704-0559.

Type of Request: New Collection.

Number of Respondents: 5,000.

Responses per Respondent: 1.

Annual Responses: 5,000.

Average Burden Per Response: 2 minutes.

Annual Burden Hours: 167.

Needs and Uses: The information collection requirement is necessary to establish a Defense Enrollment Eligibility Reporting System (DEERS) record and surrogate association for issuance of a DoD Self-Service (DS) Logon. A surrogate may be established: (1) As the custodian of an unmarried minor child(ren) of a deceased Service member who is under age 18, who is at least 18 but under 23 and attending school full-time, or who is incapacitated. (2) As the agent of an incapacitated dependent (e.g., spouse, parent). (3) As the agent of a wounded, ill, or incapacitated Service member.

Affected Public: Individuals or Households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Sehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: July 23, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison
Officer, Department of Defense.

[FR Doc. 2018-16043 Filed 7-26-18; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Government-Owned Inventions; Available for Licensing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy (DoN) announces the availability of the inventions listed below, assigned to the United States Government, as represented by the Secretary of the Navy, for domestic and foreign licensing by the Department of the Navy.

ADDRESSES: Requests for copies of the patents cited should be directed to Naval Surface Warfare Center, Crane Div, Code OOL, Bldg. 2, 300 Highway 361, Crane, IN 47522-5001.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Monsey, Naval Surface Warfare Center, Crane Div, Code OOL, Bldg. 2, 300 Highway 361, Crane, IN 47522-5001, Email Christopher.Monsey@navy.mil, 812-854-2777.

SUPPLEMENTARY INFORMATION: The following patents are available for licensing: Patent No. 9,987,996 (Navy Case No. 200223): VEHICLE WITH AT LEAST ONE MULTIPURPOSE EQUIPMENT ITEM MOUNTED ON A WINCH AND ASSOCIATED METHODS OF USE//Patent No. 10,001,417 (Navy Case No. 2001416): ADAPTIVE HEAT FLOW CALORIMETER//and Patent No. 10,006,770 (Navy Case No. 200402): REMOTE LOCATION DETERMINATION SYSTEM.

Authority: 35 U.S.C. 207, 37 CFR part 404.

Dated: July 23, 2018.

James Edward Mosimann III,

Lieutenant, Judge Advocate General's Corps,
U.S. Navy, Alternate Federal Register Liaison
Officer.

[FR Doc. 2018-16017 Filed 7-26-18; 8:45 am]

BILLING CODE 3810-FF-P

DEPARTMENT OF EDUCATION

[Docket ID ED-2017-FSA-0047]

Privacy Act of 1974; Matching Program

AGENCY: Department of Education.

ACTION: Notice of a new matching program.

SUMMARY: This is a Notice of a new matching program between the Department of Education (ED) and the Defense Manpower Data Center (DMDC) of the U.S. Department of Defense (DoD). This is a new matching notice upon expiration of the previously published 18-month Computer Matching agreement August 1, 2017. It was originally established on February 1, 2010.

DATES: Submit your comments on the proposed matching program or before August 27, 2018.

The matching program will go into effect at the later of the following two dates: (1) The date of the last signatory to this CMA as set forth in Article XIX, below, or (2) 30 days after the publication of this notice on July 27, 2018, unless the matching notice needs to be changed as a result of public comment. The Department will publish any changes resulting from public comment.

The matching program will continue for 18 months after the applicable date and may be extended for an additional 12 months, if the respective agency Data Integrity Boards (DIBS) determine that the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met. The life of this CMA is estimated to cover the 18-month period from August 28, 2018 through February 27, 2020.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to www.regulations.gov to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the "help" tab.

- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments, address them to Marya Dennis, Management and Program Analyst, U.S. Department of Education, Federal Student Aid, Union Center Plaza, 830 First Street NE, Washington, DC 20002-5345.

Privacy Note: ED's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal

eRulemaking Portal at www.regulations.gov. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Ms. Marya Dennis, Management and Program Analyst, U.S. Department of Education, Federal Student Aid, Union Center Plaza, 830 First Street NE, Washington, DC 20002-5345. Telephone: (202) 377-3385.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION: We provide this notice in accordance with 5 U.S.C. 552a (commonly known as the Privacy Act of 1974, as amended); Office of Management and Budget (OMB) Final Guidance Interpreting the Provisions of Public Law 100-503, the Computer Matching and Privacy Protection Act of 1988, 54 FR 25818 (June 19, 1989); and OMB Circular A-108, 81 FR 94424 (December 23, 2016).

Under sections 420R and 473(b) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1070h and 20 U.S.C. 1087mm(b)), the Secretary of Defense must provide the Secretary of Education with information to identify the children of military personnel who have died as a result of their military service in Iraq or Afghanistan after September 11, 2001, to determine if the child is eligible for increased amounts of title IV, HEA program assistance. DoD and ED have determined that matching records contained in the DoD DMDC system and the Defense Enrollment Eligibility Reporting System (DEERS) against ED's Federal Student Aid Application File (18-11-01) is the only practical method that the agencies can use to meet the statutory requirements of the HEA.

The prior Computer Matching Agreement (CMA) was published in the **Federal Register** on June 30, 2017 (82 FR 29856). ED and DoD are now re-

establishing the CMA through this notice.

Participating Agencies

ED and DoD.

Authority for Conducting the Matching Program

Sections 420R and 473(b) of the HEA (20 U.S.C. 1070h and 20 U.S.C. 1087mm(b)) and 5 U.S.C. 552a.

Purpose(s)

This matching program identifies children whose parent or guardian was a member of the Armed Forces of the United States and died as a result of performing military service in Iraq or Afghanistan after September 11, 2001. These children (referred to as qualifying students) may be eligible for a greater amount of title IV, HEA program assistance. A qualifying student must have been age 24 or younger at the time of the parent's or guardian's death, or, if older than 24, enrolled part-time or full-time in an institution of higher education at the time of the parent's or guardian's death. Beginning July 1, 2010, students who are otherwise qualified children of deceased U.S. military who meet the requirements of section 420R of the HEA (20 U.S.C. 1070h) may also be eligible for higher amounts of title IV, HEA program assistance.

Categories of Individuals

The individuals whose records are included in this matching program are dependents of service personnel who died as a result of performing their military service in Iraq or Afghanistan after September 11, 2001, which records are located in the DoD DMDC and DEERS systems, and all students who complete a Free Application for Federal Student Aid.

Categories of Records

DoD uses the following data elements in this matching program: Dependent's Name, Date of Birth and SSN—extracted from DEERS; and Parent or Guardian's Date of Death—extracted from DMDC Data Base.

ED uses the SSN, date of birth, and the first two letters of an applicant's last name to match applicant records.

System(s) of Records

ED system of records: Federal Student Aid Application File (18–11–01) (76 FR 46774, August 3, 2011).

DoD system of records: DMDC 01, Defense Manpower Data Center Data Base (76 FR 72391) (November 23, 2011), and DMDC 02 DoD Defense Enrollment Eligibility Reporting

Systems (DEERS) (81 FR 49210) (July 27, 2016).

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (such as, braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available through the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

James F. Manning,

Acting Chief Operating Officer, Federal Student Aid.

[FR Doc. 2018–16092 Filed 7–26–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR18–52–001.

Applicants: DTE Gas Company.

Description: Tariff Filing per 284.123(b),(e)/: Operating Statement Amendment to be effective 6/1/2018.

Filed Date: 7/19/18.

Accession Number: 201807195053.

Comments/Protests Due: 5 p.m. ET 7/30/18.

Docket Number: PR18–67–000.

Applicants: Pacific Gas and Electric Company.

Description: Tariff filing per 284.123(b),(e)+(g)/.224: Revisions to Statement of Operating Conditions: to be effective 1/1/2018.

Filed Date: 7/20/18.

Accession Number: 201807205000.

Comments Due: 5 p.m. ET 8/10/18.

284.123(g) Protests Due: 5 p.m. ET 9/18/18.

Docket Number: PR18–68–000.

Applicants: DTE Gas Company.

Description: Tariff Filing per 284.123(b),(e)/: DTE Gas Company Rate Filing to be effective 6/1/2018.

Filed Date: 7/20/18.

Accession Number: 201807205136.

Comments/Protests Due: 5 p.m. ET 8/10/18.

Docket Numbers: RP18–985–000.

Applicants: Eastern Shore Natural Gas Company.

Description: Compliance filing Incremental Rates 2017 Expansion Project to be effective 7/20/2018.

Filed Date: 7/19/18.

Accession Number: 20180719–5111.

Comments Due: 5 p.m. ET 7/31/18.

Docket Numbers: RP18–986–000.

Applicants: Dominion Energy Carolina Gas Transmission.

Description: § 4(d) Rate Filing: DECG—July 2018 Administrative Changes to be effective 8/20/2018.

Filed Date: 7/20/18.

Accession Number: 20180720–5037.

Comments Due: 5 p.m. ET 8/1/18.

Docket Numbers: RP18–987–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Non-Conforming—Atlantic Sunrise to be effective 8/20/2018.

Filed Date: 7/20/18.

Accession Number: 20180720–5050.

Comments Due: 5 p.m. ET 8/1/18.

Docket Numbers: RP18–988–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Central Penn Line—Tariff References to be effective 8/20/2018.

Filed Date: 7/20/18.

Accession Number: 20180720–5063.

Comments Due: 5 p.m. ET 8/1/18.

Docket Numbers: RP18–989–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Atlantic Sunrise Tariff Rate Filing to be effective 8/20/2018.

Filed Date: 7/20/18.

Accession Number: 20180720–5064.

Comments Due: 5 p.m. ET 8/1/18.

Docket Numbers: RP18–990–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: List of Non-Conforming Service Agreements (Atlantic Sunrise) to be effective 8/20/2018.

Filed Date: 7/20/18.

Accession Number: 20180720–5078.

Comments Due: 5 p.m. ET 8/1/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: July 23, 2018.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2018-16084 Filed 7-26-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18-2031-000]

Hudson Shore Energy Partners LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of HUDSON SHORE ENERGY PARTNERS LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and

assumptions of liability, is August 8, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: July 19, 2018.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2018-16083 Filed 7-26-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2833-108]

Public Utility District No. 1 of Lewis County, Washington; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

July 23, 2018.

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection:

a. *Type of Application:* Proposed Revisions to Whitewater Boating Take-Out Plan and Project Boundary.

b. *Project No:* 2833-108.

c. *Date Filed:* March 1 and 2, 2018, and supplemented on June 14, 2018.

d. *Applicant:* Public Utility District No. 1 of Lewis County, Washington (licensee).

e. *Name of Project:* Cowlitz Falls Hydroelectric Project.

f. *Location:* The project is located on the Cowlitz River in Lewis County Washington.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a-825r.

h. *Applicant Contact:* Joseph M. First, Project Superintendent, PUD No. 1 of Lewis County, P.O. Box 1387, Morton, WA 98356; (360) 497-5351.

i. *FERC Contact:* Jon Cofrancesco at (202) 502-8951, or jon.cofrancesco@ferc.gov.

j. *Deadline for filing comments, motions to intervene, and protests:* August 22, 2018.

The Commission strongly encourages electronic filing. Please file motions to intervene, protests, and comments using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P-2833-108. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee filed an application proposing revisions to the project's whitewater boating take-out site plan approved by the Commission's Order Modifying and Approving Plan for Whitewater Boating Take-out Site issued June 22, 2006. The proposed revisions would make changes to the existing approved Cooper Canyon Creek Take-Out Site, including unlimited open-gate access to the take-

out site, elimination of existing boater insurance requirements, elimination of the 1000-foot-long portage from the existing parking area to the entrance to the access road (340 spur road), additional parking at the take-out site, and changes to the project boundary associated with the 340 spur road and parking area. In addition, the licensee requests Commission approval of its conceptual plans to develop two alternate take-out sites in the area for use when the Cooper Canyon Creek Take-Out Site is inaccessible.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling 202-502-8371. This filing may also be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 866-208-3676 or email FERCOnlineSupport@ferc.gov, for TTY, call 202-502-8659. A copy is also available for inspection and reproduction at the address in item (h) above. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS"; "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address,

and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018-16108 Filed 7-26-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG18-109-000.

Applicants: Blue Summit Interconnection, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Blue Summit Interconnection, LLC.

Filed Date: 7/20/18.

Accession Number: 20180720-5188.

Comments Due: 5 p.m. ET 8/10/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18-2043-000.

Applicants: Alabama Power Company.

Description: § 205(d) Rate Filing: Cooperative Energy NITSA Amendment (adding new Article 7) to be effective 8/3/2018.

Filed Date: 7/20/18.

Accession Number: 20180720-5071.

Comments Due: 5 p.m. ET 8/10/18.

Docket Numbers: ER18-2044-000.

Applicants: Alabama Power Company.

Description: § 205(d) Rate Filing: Cooperative Energy Interconnection Agreement Amendment (adding Jasper East IP) to be effective 8/3/2018.

Filed Date: 7/20/18.

Accession Number: 20180720-5072.

Comments Due: 5 p.m. ET 8/10/18.

Docket Numbers: ER18-2045-000.

Applicants: NorthWestern Corporation.

Description: Tariff Cancellation: Notice of Cancellation: SA 827 Agreement for Remediation with GFDA Agritech Park to be effective 7/23/2018.

Filed Date: 7/20/18.

Accession Number: 20180720-5092.

Comments Due: 5 p.m. ET 8/10/18.

Docket Numbers: ER18-2046-000.

Applicants: American Transmission Systems, Incorporated, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: ATSI submits ECSAs, Service Agreement Nos. 4893, 4894, 4895, 4931, 4932 to be effective 9/20/2018.

Filed Date: 7/20/18.

Accession Number: 20180720-5118.

Comments Due: 5 p.m. ET 8/10/18.

Docket Numbers: ER18-2047-000.

Applicants: ISO New England Inc.

Description: Filing of Permanent De-List Bids and Retirement De-List Bids for 2022-23 Forward Capacity Auction (FCA 13) of ISO New England, Inc.

Filed Date: 7/20/18.

Accession Number: 20180720-5121.

Comments Due: 5 p.m. ET 8/10/18.

Docket Numbers: ER18-2048-000.

Applicants: New York Independent System Operator, Inc.

Description: § 205(d) Rate Filing: Revisions to implement historic fixed price TCC extensions to be effective 9/19/2018.

Filed Date: 7/20/18.

Accession Number: 20180720-5132.

Comments Due: 5 p.m. ET 8/10/18.

Docket Numbers: ER18-2049-000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2018-07-20 Attachment X Revisions to Expedite Phase I of the DPP to be effective 9/19/2018.

Filed Date: 7/20/18.

Accession Number: 20180720-5192.

Comments Due: 5 p.m. ET 8/10/18.

Docket Numbers: ER18-2050-000.

Applicants: San Diego Gas & Electric Company, Sempra Gas & Power Marketing, LLC.

Description: Joint Application for Approval of Affiliate Transaction Pursuant to Section 205 of the Federal Power Act of San Diego Gas & Electric Company, et al.

Filed Date: 7/20/18.

Accession Number: 20180720-5195.

Comments Due: 5 p.m. ET 8/10/18.

Docket Numbers: ER18-2051-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3283 NextEra Energy & Sunflower Meter Agent Agr Cancellation to be effective 7/31/2018.

Filed Date: 7/23/18.

Accession Number: 20180723-5050.

Comments Due: 5 p.m. ET 8/13/18.

The filings are accessible in the Commission's eLibrary system by

clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: July 23, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018-16088 Filed 7-26-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP18-980-000.

Applicants: Panther Interstate Pipeline Energy, LLC.

Description: Tariff Cancellation: PIPE Resubmission of Tariff Cancellation Filing to be effective 7/17/2018.

Filed Date: 7/17/18.

Accession Number: 20180717-5074.

Comments Due: 5 p.m. ET 7/30/18.

Docket Numbers: RP18-982-000.

Applicants: Eastern Shore Natural Gas Company.

Description: § 4(d) Rate Filing: Negotiated Rate and Non-Conforming Agreements to be effective 7/20/2018.

Filed Date: 7/18/18.

Accession Number: 20180718-5088.

Comments Due: 5 p.m. ET 7/30/18.

Docket Numbers: RP18-983-000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rate—Exelon 8950525 eff 11-01-2018 to be effective 11/1/2018.

Filed Date: 7/18/18.

Accession Number: 20180718-5103.

Comments Due: 5 p.m. ET 7/30/18.

Docket Numbers: RP18-984-000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing: Equitrans' Clean Up Filing—July 2018 to be effective 8/18/2018.

Filed Date: 7/18/18.

Accession Number: 20180718-5115.

Comments Due: 5 p.m. ET 7/30/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: July 19, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018-16081 Filed 7-26-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RD18-4-000]

Commission Information Collection Activities (FERC-725G2¹); Comment Request; Revision

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is submitting its information collection, FERC-725G2¹ (Reliability Standards for the Bulk Power System: PRC Reliability Standards) to the Office of Management and Budget (OMB) for review of the information collection requirements.

¹ Commission staff is using the FERC-725G2 is a temporary "place holder" information collection for this 30-day notice. FERC-725G information collection (OMB Control No. 1902-0252) is pending review at OMB in an unrelated item and only one item per OMB Control No. can be pending OMB review at a time. In order to submit this timely, to OMB, we are using a temporary place holder.

Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission previously issued a Notice in the **Federal Register** on May 16, 2018, requesting public comments. The Commission received no comments on the FERC-725G2 and is making this notation in its submittal to OMB.

DATES: Comments on the collection of information are due August 27, 2018.

ADDRESSES: Comments filed with OMB, identified by the OMB Control No.: 1902-0281, should be sent via email to the Office of Information and Regulatory Affairs: oir_submission@omb.gov. Attention: Federal Energy Regulatory Commission Desk Officer. The Desk Officer may also be reached via telephone at 202-395-8528. A copy of the comments should also be sent to the Commission, in Docket No. RD18-4-000, by either of the following methods:

- *eFiling at Commission's Website:* <http://www.ferc.gov/docs-filing/efiling.asp>.

- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <http://www.ferc.gov/help/submission-guide.asp>. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at: (866) 208-3676 (toll-free), or (202) 502-8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <http://www.ferc.gov/docs-filing/docs-filing.asp>.

FOR FURTHER INFORMATION CONTACT:

Ellen Brown may be reached by email at DataClearance@FERC.gov, telephone at (202) 502-8663, and fax at (202) 273-0873.

SUPPLEMENTARY INFORMATION:

Title: FERC-725G2, Reliability Standards for the Bulk Power System: PRC Reliability Standards.

OMB Control No.: 1902-0281.

Type of Request: Revision of FERC-725G2 information collection requirements as discussed in Docket No. RD18-4.

Abstract: The information collected by the FERC-725G2 is required to implement the statutory provisions of section 215 of the Federal Power Act (FPA) (16 U.S.C. 824o). Section 215 of the FPA buttresses the Commission's

efforts to strengthen the reliability of the interstate grid.

On March 16, 2018, the North American Electric Reliability Corporation (NERC, the Commission-approved ERO) submitted for Commission approval proposed Reliability Standard PRC-025-2. Reliability Standard PRC-025-2 addresses setting load-responsive protective relays associated with generation facilities at a level to prevent unnecessary tripping of generators during a system disturbance for conditions that do not pose a risk of damage to the associated equipment. Reliability Standard PRC-025-2 also improves upon the retired Reliability Standard PRC-025-1² by addressing certain relay setting application issues and by clarifying certain terminology and references. NERC requested that the Commission approve the Reliability Standard and find that the approved standard is just, reasonable, not unduly

discriminatory or preferential, and in the public interest. NERC also requested that the Commission approve: (i) The associated Implementation Plan; (ii) the associated Violation Risk Factors (VRFs) and Violation Severity Levels (VSLs), which remain unchanged from Reliability Standard PRC-025-1; and (iii) the retirement of currently-effective Reliability Standard PRC-025-1.

Reliability Standard PRC-025-2 became effective on 7/1/2018, the first day of the first calendar quarter after the effective date of the applicable governmental authority's order approving the standard. NERC's Implementation Plan approved phased-in compliance dates after the effective date of Reliability Standard PRC-025-2.³

On May 2, 2018, pursuant to the relevant authority delegated to the Director, Office of Electric Reliability under 18 CFR 385.713 (2017) Reliability Standard PRC-025-2 and the retirement

of Reliability Standard PRC-025-1 was approved.

Type of Respondents: Generator Owner (GO), Transmission Owner (TO), and Distribution Provider (DP).

*Estimate of Annual Burden:*⁴ Details follow on the changes in Docket No. RD18-4-000 to Reliability Standard FERC-725G2.

Net Effect to Burden for FERC-725G2: Due to the retirement of Reliability Standard PRC-025-1 and implementation of Reliability Standard PRC-025-2, the number of respondents is reduced by 25, and the number of annual burden hours is reduced by 550 hours. (The net changes are due to a change in the number of affected entities on the NERC Registry.) The burden per respondent for Reliability Standard PRC-025-2 remains 22 hours (total for both one-time and ongoing burden, similar to the now-retired Reliability Standard PRC-025-1.)

FERC-725G2, MANDATORY RELIABILITY STANDARD PRC-025-2, IN DOCKET NO. RD18-4-000

Entity	Number of respondents ⁵	Annual number of responses per respondent	Annual number of responses	Average burden hours and cost per response ⁶	Total annual burden hours and total annual cost	Cost per respondent
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1) = (6)
(One-time) Review & documentation of relay settings to ensure compliance.	994 GO/TO/DP	1	994	20 hrs.; \$1,298.20 ...	19,880 hours; \$1,290,410.80.	\$1,298.20
(On-going) Record Retention (of compliance records for R1 and M1, for 3 years or until mitigation complete).	994 GO/TO/DP	1	994	2 hrs.; \$62.32	1,988 hours; \$61,946.08.	62.32

FERC-725G, MANDATORY RELIABILITY STANDARD PRC-025-1, RETIREMENT IN DOCKET NO. RD18-4-000

Entity	Number of respondents	Annual number of responses per respondent	Annual number of responses	Average burden hours and cost ⁷ per response	Total annual burden hours and total annual cost	Cost per respondent ⁸
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1) = (6)
(One-time) Review & documentation of relay settings to ensure compliance.(reduction).	1,019 GO/DP/TO	1	1,019	20 hrs.; \$1,192.40 (reduction).	20,380 hours; \$1,215,055.60 (reduction).	\$1,192.40 (reduction).
(On-going) Record Retention (of compliance records for R1 and M1, for 3 years or until mitigation complete) (reduction).	1,019 GO/DP/TO	1	1,019	2 hrs.; \$57.90 (reduction).	2,038 hours; \$59,000.10 (reduction).	57.90 (reduction).

² <http://www.nerc.net/standardsreports/standardssummary.aspx>.

³ See NERC's Implementation Plan at https://www.nerc.com/pa/Stand/Project%20201604%20Modifications%20to%20PRC0251%20DL/Project_2016_04_Implementation_Plan_Clean_01092018.pdf.

⁴ Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information

collection burden, refer to 5 Code of Federal Regulations 1320.3.

⁵ According to the NERC compliance registry as of March 9, 2018, NERC has registered 415 distribution providers (DP), 985 generator owners (GO) and 336 transmission owners (TO). However, under NERC's compliance registration program, entities may be registered for multiple functions, so these numbers incorporate some double counting. The number of unique entities responding will be approximately 994 entities registered as a transmission owner, a distribution provider, or a generator owner that is also a transmission owner and/or a distribution owner. This estimate assumes

all of the unique entities apply load-responsive protective relays.

⁶ The hourly cost (for salary plus benefits) uses the figures from the Bureau of Labor Statistics, May 2017, for two positions involved in the reporting and recordkeeping requirements. These figures include salary (https://www.bls.gov/oes/current/naics2_22.htm) and benefits (<http://www.bls.gov/news.release/ecec.nr0.htm>) and are: Engineer: \$64.91/hour, and File Clerk: \$31.16/hour. Hourly cost for the engineer are used for the one-time costs, and hourly cost for the file clerk are used for the ongoing record retention.

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 19, 2018.

Kimberly D. Bose,
Secretary.

[FR Doc. 2018-16015 Filed 7-26-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ID-8512-000]

Miller, Paul J.; Notice of Filing

Take notice that on July 18, 2018, Paul J. Miller, submitted for filing an application for authority to hold interlocking positions, pursuant to section 305(b) of the Federal Power Act, 16 U.S.C. 825d(b) and section 45.8 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR part 45.8 (2018).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as

appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5:00 p.m. Eastern Time on August 8, 2018.

Dated: July 19, 2018.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2018-16086 Filed 7-26-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP18-523-000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on July 13, 2018, Columbia Gas Transmission, LLC (Columbia), 700 Louisiana Street, Suite 700, Houston, Texas 77002-2700, filed in the above referenced docket, a prior notice request pursuant to sections 157.205 and 157.216 of the Commission's regulations under the Natural Gas Act (NGA) and Columbia's blanket certificate issued in Docket No. CP83-76-000, for authorization to (1) plug and abandon four injection/withdrawal (I/W) wells (Benton Well 9507 and Laurel Wells 9097, 9239, and 9285), (2) abandon and convert one I/W well to an observation well (Benton Well 7612), and (3) abandon associated pipelines and appurtenances located at Benton and Laurel Storage Fields in

Hocking County, Ohio, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may also be viewed on the web at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208-3676, or TTY, contact (202) 502-8659.

Any questions regarding this application may be directed to Linda Farquhar, Manager, Project Determinations & Regulatory Administration, Columbia Gas Transmission, LLC, 700 Louisiana Street, Suite 700, Houston, Texas 77002-2700, at (832) 320-5685 or fax (832) 320-6685 or linda_farquhar@transcanada.com.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

⁷ GO = Generator Owner, DP = Distribution Provider, TO = Transmission Owner, each of which applies load-responsive protective relays at the terminals of the Elements listed in the proposed standard at section 3.2 (Facilities).

⁸ The estimated hourly costs (salary plus benefits) are based on Bureau of Labor Statistics (BLS) information May 2014, (at http://bls.gov/oes/current/naics3_221000.htm#17-0000) for an electrical engineer (\$59.62/hour for review and documentation), and for a file clerk (\$28.95/hour for record retention). Those figures (and the number of respondents) were used when the standard was approved and added to the OMB inventory. Hourly cost for the engineer are used for the one-time costs, and hourly cost for the file clerk are used for the ongoing record retention.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's website (www.ferc.gov) under the "e-Filing" link.

Dated: July 23, 2018.

Kimberly D. Bose,
Secretary.

[FR Doc. 2018-16107 Filed 7-26-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18-2003-000]

Lorenzo Wind, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding Lorenzo Wind, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission,

888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: July 20, 2018.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2018-16078 Filed 7-26-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP18-13-000]

Notice of Schedule for Environmental Review of the Columbia Gas Transmission, Llc Line 8000 Replacement Project

On November 3, 2017, Columbia Gas Transmission, LLC filed an application in Docket No. CP18-13-000 requesting a Certificate of Public Convenience and Necessity pursuant to Sections 7(b) and (c) of the Natural Gas Act to construct, operate, and abandon certain natural gas pipeline facilities in Mineral County, West Virginia and Allegany County, Maryland. The proposed project is known as the Line 8000 Replacement Project (Project) and is part of Columbia's multi-year, comprehensive modernization program. The Project would not increase capacity and would continue to serve the Maryland distribution markets. According to Columbia, its Project would increase system reliability, thereby greatly reducing the risk of interruptions to Columbia's customers.

On November 17, 2017, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's Environmental

Assessment (EA) for the Project. This instant notice identifies the FERC staff's planned schedule for the completion of the EA for the Project.

Schedule for Environmental Review

Issuance of EA—August 29, 2018
90-day Federal Authorization Decision
Deadline—November 27, 2018

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

The Line 8000 Replacement Project would consist of:

- Replacement of about 13.25 miles of existing 12-inch-diameter bare steel pipeline, with approximately 13.54 miles of new, coated 12-inch-diameter natural gas transmission pipeline in five sections and four modification points along Line 8000 and Lateral Line 8006;
- replacement of about 0.54 miles of existing 4-inch-diameter bare steel pipeline, with approximately 0.67 miles of new coated 4-inch-diameter natural gas transmission pipeline along Lateral Lines 8225 and 8244;
- installation of two new pig¹ launcher and receiver sites and four new mainline valves associated with pipeline facilities;
- modifications/abandonment of three existing mainline valves and three existing side tap valve sites;
- modification of tie-ins at two regulator stations; and
- abandonment of 13 active residential taps and 109 inactive taps.

Background

On December 19, 2017, the Commission issued a *Notice of Intent to Prepare an Environmental Assessment for the Proposed Line 8000 Replacement Project and Request for Comments on Environmental Issues* (NOI). The NOI was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the NOI, the Commission received comments from Columbia Gas of Maryland, Inc., Direct Energy Business Marketing, LLC, the West Virginia Division of Culture and History, the Maryland Department of Environment, and one landowner. The comments addressed the conversion to an alternate

¹ A "pig" is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

energy source for customers who would be affected by the abandonment of residential farm taps, the cost of the Project, cultural resources, air quality, stormwater and erosion, water resources, and land use. All substantive comments will be addressed in the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to www.ferc.gov/docs-filing/esubscription.asp.

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208-FERC or on the FERC website (www.ferc.gov). Using the "eLibrary" link, select "General Search" from the eLibrary menu, enter the selected date range and "Docket Number" excluding the last three digits (i.e., CP18-13), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208-3676, TTY (202) 502-8659, or at FERCOnlineSupport@ferc.gov. The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: July 20, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018-16080 Filed 7-26-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC18-111-000.

Applicants: Grand River Wind LLC, Trishe Wind Ohio, LLC.

Description: Amendment to June 25, 2018 Application for Approval Pursuant under Section 203 of the Federal Power Act of Grand River Wind LLC, et al.

Filed Date: 7/18/18.

Accession Number: 20180718-5145.

Comments Due: 5 p.m. ET 7/25/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15-1218-005.

Applicants: Solar Star California XIII, LLC.

Description: Compliance filing: Solar Star California XIII MBR Tariff Change in Status to be effective 7/20/2018.

Filed Date: 7/19/18.

Accession Number: 20180719-5074.

Comments Due: 5 p.m. ET 8/9/18.

Docket Numbers: ER16-38-003.

Applicants: Kingbird Solar A, LLC.

Description: Compliance filing: Kingbird Solar A LLC Notice of Change in Category Status to be effective 7/20/2018.

Filed Date: 7/19/18.

Accession Number: 20180719-5077.

Comments Due: 5 p.m. ET 8/9/18.

Docket Numbers: ER18-2036-000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of Service Agreement No. 5044; Queue No. AB1-013 to be effective 5/21/2018.

Filed Date: 7/18/18.

Accession Number: 20180718-5130.

Comments Due: 5 p.m. ET 8/8/18.

Docket Numbers: ER18-2037-000.

Applicants: Boulder Solar Power, LLC.

Description: § 205(d) Rate Filing: Amendments to Boulder Solar Shared Facilities Agreement No. 1 to be effective 7/19/2018.

Filed Date: 7/19/18.

Accession Number: 20180719-5028.

Comments Due: 5 p.m. ET 8/9/18.

Docket Numbers: ER18-2038-000.

Applicants: Cogentrix Virginia Financing Holding Company, LLC.

Description: Tariff Cancellation: Notice of Cancellation to be effective 7/20/2018.

Filed Date: 7/19/18.

Accession Number: 20180719-5035.

Comments Due: 5 p.m. ET 8/9/18.

Docket Numbers: ER18-2039-000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2019-07-19 PSCo-TSGT Non-Cnfmf LGIA-Rifle SS-0.0.0-Filing to be effective 7/19/2018.

Filed Date: 7/19/18.

Accession Number: 20180719-5048.

Comments Due: 5 p.m. ET 8/9/18.

Docket Numbers: ER18-2040-000.

Applicants: James River Genco, LLC.

Description: Tariff Cancellation: Notice of Cancellation to be effective 7/20/2018.

Filed Date: 7/19/18.

Accession Number: 20180719-5049.

Comments Due: 5 p.m. ET 8/9/18.

Docket Numbers: ER18-2041-000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: PSCo-TSGT-JM Shafer-E&P-459-0.1.0-NOC to be effective 7/20/2018.

Filed Date: 7/19/18.

Accession Number: 20180719-5054.

Comments Due: 5 p.m. ET 8/9/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: July 19, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018-16082 Filed 7-26-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15-2593-009; ER14-661-015; ER15-1475-010; ER15-54-009; ER15-55-009; ER16-38-004; ER16-39-004; ER15-1218-006; ER15-2224-004; ER16-1154-007.

Applicants: Desert Stateline LLC, SG2 Imperial Valley LLC, North Star Solar, LLC, Lost Hills Solar, LLC, Blackwell Solar, LLC, Kingbird Solar A, LLC, Kingbird Solar B, LLC, Solar Star Colorado XIII, LLC, Solar Star Colorado III, LLC, Parrey, LLC.

Description: Notice of Non-Material of Change in Status of Desert Stateline LLC, et al.

Filed Date: 7/19/18.

Accession Number: 20180719-5120.

Comments Due: 5 p.m. ET 8/9/18.

Docket Numbers: ER16–39–003.
Applicants: Kingbird Solar B, LLC.
Description: Compliance filing: Kingbird Solar B LLC MBR Tariff Change in Status to be effective 7/20/2018.
Filed Date: 7/19/18.
Accession Number: 20180719–5073.
Comments Due: 5 p.m. ET 8/9/18.
Docket Numbers: ER17–351–005; ER17–354–005; ER17–2162–004; ER17–2163–004.
Applicants: American Falls Solar, LLC, American Falls Solar II, LLC, SunE Beacon Site 2 LLC, SunE Beacon Site 5 LLC.
Description: Notice of Change in Status of American Falls Solar, LLC, et al.
Filed Date: 7/19/18.
Accession Number: 20180719–5117.
Comments Due: 5 p.m. ET 8/9/18.
Docket Numbers: ER18–1669–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Amendment: 2018–07–20 SA 3115 LCM–ELL Substitute Original GIA (C042) to be effective 6/10/2018.
Filed Date: 7/20/18.
Accession Number: 20180720–5042.
Comments Due: 5 p.m. ET 8/10/18.
Docket Numbers: ER18–1955–001.
Applicants: GridLiance High Plains LLC.
Description: Tariff Amendment: Amended SCMCN DX Formula Rate to be effective 10/1/2018.
Filed Date: 7/19/18.
Accession Number: 20180719–5109.
Comments Due: 5 p.m. ET 8/9/18.
Docket Numbers: ER18–1959–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Amendment: 2018–07–20 SA 2677 GRE–NSP Substitute 3rd Rev GIA (J278) to be effective 6/21/2018.
Filed Date: 7/20/18.
Accession Number: 20180720–5027.
Comments Due: 5 p.m. ET 7/27/18.
Docket Numbers: ER18–2042–000.
Applicants: American Transmission Systems, Incorporated, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: ATSI submits 4 ECSAs, Service Agreement Nos. 4934, 4935, 4936, and 4937 to be effective 9/20/2018.
Filed Date: 7/20/18.
Accession Number: 20180720–5060.
Comments Due: 5 p.m. ET 8/10/18.
 Take notice that the Commission received the following electric securities filings:
Docket Numbers: ES18–47–000.
Applicants: Transource West Virginia, LLC.

Description: Application under Section 204 of the Federal Power Act for Authorization to Issue Securities of Transource West Virginia, LLC.

Filed Date: 7/20/18.

Accession Number: 20180720–5046.

Comments Due: 5 p.m. ET 8/10/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 20, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–16085 Filed 7–26–18; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9981–30–OA]

Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office requests public nominations for scientific experts to form a CASAC ad hoc panel to provide advice through the chartered CASAC on the scientific and technical aspects of air quality criteria and the National Ambient Air Quality Standards (NAAQS) for ozone.

DATES: Nominations should be submitted by (August 17, 2018) per instructions below.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Notice and Request for Nominations may contact Mr. Aaron Yeow, Designated Federal

Officer (DFO), SAB Staff Office, by telephone/voice mail at (202) 564–2050 or via email at yeow.aaron@epa.gov. General information concerning the CASAC can be found on the following website: <http://www.epa.gov/casac>.

SUPPLEMENTARY INFORMATION:

Background: The Clean Air Scientific Advisory Committee (CASAC) was established under section 109(d)(2) of the Clean Air Act (CAA or Act) (42 U.S.C. 7409) as an independent scientific advisory committee. The CASAC provides advice, information and recommendations on the scientific and technical aspects of air quality criteria and NAAQS under sections 108 and 109 of the Act. The CASAC shall also: Advise the EPA Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS; describe the research efforts necessary to provide the required information; advise the EPA Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity; and advise the EPA Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS.

As amended, 5 U.S.C., App. Section 109(d)(1) of the Clean Air Act (CAA) requires that EPA carry out a periodic review and revision, as appropriate, of the air quality criteria and the NAAQS for the six “criteria” air pollutants, including ozone. With the publication of the National Ambient Standards for Ozone (80 FR 65292) on October 26, 2015, the Agency completed its most recent review of the Ozone NAAQS. The CASAC's Ozone Review Panel for that review cycle was formed in January 2009 and completed its work in July 2014.

This **Federal Register** notice solicitation is seeking nominations for subject matter experts to serve on the CASAC Ozone Review Panel for the next review of the Ozone NAAQS that begins in fiscal year (FY) 2018. The Panel will be charged with reviewing the science and policy assessments, and related documents, that form the basis for the EPA's review of the Ozone NAAQS, and will provide advice through the Chartered CASAC.

The CASAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA). As a Federal Advisory Committee, the CASAC conducts business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App.

2) and related regulations. The CASAC and the CASAC Ozone Review Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Request for Nominations: The SAB Staff Office is seeking nominations of nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone. Experts are sought in: Air quality, atmospheric science and chemistry, causal inference, dosimetry, toxicology, controlled clinical exposure, epidemiology, biostatistics, human exposure modeling, risk assessment/modeling, uncertainty analysis, ecology and effects on welfare and the environment, and environmental economics.

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate qualified individuals in the areas of expertise described above. Individuals may self-nominate. Nominations should be submitted in electronic format (preferred) using the online nomination form under "Public Input on Membership" on the CASAC web page at <http://www.epa.gov/casac>. To be considered, all nominations should include the information requested below. EPA values and welcomes diversity. All qualified candidates are encouraged to apply regardless of sex, race, disability or ethnicity. Nominations should be submitted by (August 17, 2018).

The following information should be provided on the nomination form: Contact information for the person making the nomination; contact information for the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's *curriculum vitae*; and a biographical sketch of the nominee indicating current position, educational background; research activities; sources of research funding for the last two years; and recent service on other national advisory committees or national professional organizations. Persons having questions about the nomination process or the public comment process described below, or who are unable to submit nominations through the CASAC website, should contact the DFO, as identified above. The DFO will acknowledge receipt of nominations and will invite the nominee to provide any additional information that the nominee feels would be useful in considering the nomination. The names and biosketches of qualified nominees identified by respondents to this **Federal Register** notice, and additional experts identified by the SAB Staff Office, will be posted

in a List of Candidates on the CASAC website at <http://www.epa.gov/casac>. Public comments on each List of Candidates will be accepted for 21 days from the date the list is posted. The public will be requested to provide relevant information or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates.

For the EPA SAB Staff Office, a balanced review panel includes candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the charge. In forming this expert panel, the SAB Staff Office will consider public comments on the List of Candidates, information provided by the candidates themselves, and background information independently gathered by the SAB Staff Office. Selection criteria to be used for panel membership include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; (e) skills working in committees, subcommittees and advisory panels; and, (f) for the panel as a whole, diversity of expertise and viewpoints.

The SAB Staff Office's evaluation of an absence of financial conflicts of interest will include a review of the "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency" (EPA Form 3110-48). This confidential form allows government officials to determine whether there is a statutory conflict between a person's public responsibilities (which includes membership on an EPA federal advisory committee) and private interests and activities, or the appearance of a lack of impartiality, as defined by federal regulation. The form may be viewed and downloaded from the following URL address [https://yosemite.epa.gov/sab/sabproduct.nsf/Web/Form3110-48exp2018/\\$File/EPA3110-48exp2018.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/Web/Form3110-48exp2018/$File/EPA3110-48exp2018.pdf).

The approved policy under which the EPA SAB Office selects subcommittees and review panels is described in the following document: Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board (EPA-SAB-EC-02-010), which is posted on the SAB website at <http://yosemite.epa.gov/sab/>

[sabproduct.nsf/WebFiles/OverviewPanelForm/\\$File/ec02010.pdf](http://sabproduct.nsf/WebFiles/OverviewPanelForm/$File/ec02010.pdf).

Dated: July 19, 2018.

Khanna Johnston,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2018-16116 Filed 7-26-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OECA-2013-0327; FRL-9981-22-OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Portland Cement Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Portland Cement Plants (EPA ICR No. 1051.14, OMB Control No. 2060-0025), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through August 31, 2018. Public comments were previously requested via the **Federal Register** on June 29, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before August 27, 2018.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OECA-2013-0327, to: (1) EPA online using www.regulations.gov (our preferred method); or by email to: docket.oeca@epa.gov; or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats,

information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT:

Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564-2970; fax number: (202) 564-0050; email address: yellin.patrick@epa.gov.

SUPPLEMENTARY INFORMATION:

Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov, or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit: <http://www.epa.gov/dockets>.

Abstract: Owners and operators of affected facilities are required to comply with reporting and record keeping requirements for the General Provisions (40 CFR part 60, subpart A), as well as the specific requirements at 40 CFR part 60, subpart F. This includes submitting initial notifications, performance tests and periodic reports and results, and maintaining records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These reports are used by EPA to determine compliance with the standards.

Form numbers: None.

Respondents/affected entities: Portland cement plants.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart F).

Estimated number of respondents: 95 (total).

Frequency of response: Initially and semiannually.

Total estimated burden: 14,500 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$2,290,000 (per year), which includes \$767,000 in annualized capital startup and/or operation and maintenance costs.

Changes in the estimates: There is a small adjustment decrease in the respondent labor hours and the total capital and O&M costs from the most-recently approved ICR due to a decrease in the number of respondents. Consistent with past ICRs, this ICR uses the most recent data from EPA's

Greenhouse Gas Reporting Program to estimate the respondent universe, which shows a decrease of 1 respondent as compared to the previous ICR.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018-16070 Filed 7-26-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-9040-5]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564-7156 or <https://www2.epa.gov/nepa/>.

Weekly receipt of Environmental Impact Statements

Filed 07/16/2018 Through 07/20/2018 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: <https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search>.

EIS No. 20180165, Draft, USFS, CA, Williamson Rock and Pacific Crest Trail, Comment Period Ends: 09/14/2018, Contact: Chinling Chen 626-574-5255

EIS No. 20180166, Final Supplement, FHWA, AK, Juneau Access Improvements Project, Under 23 U.S.C. 139(n)(2), FTA has issued a single document that consists of a final environmental impact statement and record of decision. Therefore, the 30-day wait/review period under NEPA does not apply to this action. Contact: Tim Haugh 907-586-7418

EIS No. 20180167, Draft, NMFS, DC, Draft Amendment 11 to the 2006 Consolidated Atlantic Highly Migratory Species Fishery Management Plan, Comment Period Ends: 10/01/2018, Contact: Guy DuBeck 301-427-8503

EIS No. 20180168, Draft, USACE, AL, Mobile Harbor, Mobile, Alabama Draft Integrated General Reevaluation Report with Supplemental, Comment Period Ends: 09/10/2018, Contact: Jennifer L. Jacobson 251-690-2724

EIS No. 20180169, Final, BLM, NV, Gold Rock Mine Project, Comment Period Ends: 08/29/2018, Contact: Maria Ryan 775-289-1888

Dated: July 24, 2018.

Kelly Knight,

Acting Director, Office of Federal Activities.

[FR Doc. 2018-16094 Filed 7-26-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9980-97-OEI]

Privacy Act of 1974; System of Records

AGENCY: Office of Environmental Information, Environmental Protection Agency (EPA).

ACTION: Notice of a new system of records.

SUMMARY: The Environmental Protection Agency's (EPA) Office of Environmental Information (OEI), Office of Enterprise Information Programs (OEIP), eDiscovery Division, is giving notice that it proposes to establish a new system of records pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a). The new system of records will contain information collected using the Agency's suite of tools that search and preserve electronically stored information (ESI) in support of eDiscovery requests, Freedom of Information Act (FOIA) requests or other formal information requests. Exemptions for this system of records will be included in the Agency's update of its Privacy Act regulations at 40 CFR part 16.

DATES: Persons wishing to comment on this system of records notice must do so by. If no comments are received, the systems of records notice will become effective by August 27, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OEI-2012-0882, to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web,

cloud or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Brian K. Thompson, Acting Director, eDiscovery Division, Office of Environmental Protection Agency, U.S. Environmental Protection Agency, Mail Code 2822T, 1200 Pennsylvania Avenue NW, Washington, DC 20460; email, thompson.briank@epa.gov; telephone number, 202-564-4256.

SUPPLEMENTARY INFORMATION: The U.S. Environmental Protection Agency (EPA) plans to establish a Privacy Act system of records for information collected using its eDiscovery (electronic discovery) Enterprise Tool Suite. Depending on the specific need, the Agency will use a combination of several electronic tools that together assist with the preservation, search, processing, review and production of electronically stored information (ESI). The tool suite will be used to preserve, search, collect, sort and review ESI including email messages, word processing documents, media files, spreadsheets, presentations, scanned documents and data sets in support of legal discovery. The Agency will also use these tools to search for ESI that is responsive to requests for information submitted under FOIA or other formal information requests.

To minimize the risk of compromising the information that is being stored in the system, strict access controls have been imposed. Access to the tool suite containing records is restricted to a limited number of authorized users with the appropriate security clearances and password permissions. Access to the system is further limited by user type. System administrators have full access to the tool suite, including the ability to perform administrative functions. Other users are provided a level of access to the tool suite that is commensurate with their role in the system, allowing them to perform the functions for which they are authorized. Authorized users include federal and contract staff located throughout the country. The system is maintained in secure areas and buildings with physical access controls. The eDiscovery Enterprise Tool Suite is maintained by the Office of Environmental Information and is stored on servers located in Washington, DC, and Durham, NC. Data retrieved are stored on servers and work stations throughout the country. The

information contained in the system can be wide-ranging and potentially include emails, documents and other sources of ESI collected from custodians and may contain personally identifiable information. The information in the system will also contain the names and EPA email addresses of EPA employees, contractors, and grantees who have been identified as potential information custodians. Privacy information may be included in the ESI collected and maintained in the system. Individuals for whom records are maintained in the system include, but are not limited to, those individuals who have been identified as potential information custodians in a litigation, investigation, FOIA matter or other formal information request and those individuals whose information may appear in such records. The system will aid in protecting the privacy of individuals from unwarranted disclosure by allowing authorized users of the tool suite to identify files that contain privacy information to be protected from disclosure. EPA will safeguard individuals' privacy in a manner consistent with the Privacy Act, E-Government Act, OMB directives and other federal requirements concerning privacy. Accordingly, the privacy of individuals should not be affected.

SYSTEM NAME AND NUMBER

eDiscovery Enterprise Tool Suite, EPA-63.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

eDiscovery Enterprise Tool Suite, U.S. Environmental Protection Agency, eDiscovery Division, Office of Enterprise Information Programs, Office of Environmental Information, 1200 Pennsylvania Avenue NW, Washington, DC 20460. Records are also maintained in Research Triangle Park, 109 T.W. Alexander Drive, Durham, NC 27709.

SYSTEM MANAGER(S):

Greg Duke, eDiscovery Division, Office of Enterprise Information Programs, Office of Environmental Information, MC 3PM50, 1650 Arch Street, Philadelphia, PA 19103.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

40 U.S.C. 11315 and 44 U.S.C. 3506.

PURPOSE(S) OF THE SYSTEM:

To support the document identification and collection processes for eDiscovery, Freedom of Information Act requests and other formal information requests.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include: (1) All persons subject to a litigation hold due to a "reasonable anticipation of litigation" as determined by EPA; (2) all persons deemed a participant of past or present litigation, investigation or arbitration where EPA is involved, including civil and criminal enforcement cases and defensive litigation; and (3) individuals impacted by Freedom of Information Act (FOIA) requests, litigation or other cases in EPA.

A wide variety of individuals are covered by the system, including individuals who correspond with EPA; provide information to EPA that is subject to discovery, a FOIA request or other formal information request; or are the subject of litigation with EPA; individuals who file complaints or petitions with EPA; and individuals involved in matters with EPA as either plaintiffs or defendants in both civil and criminal matters.

CATEGORIES OF RECORDS IN THE SYSTEM:

- eDiscovery Litigation Hold Files. The litigation hold files contain the names and email addresses of EPA employees and EPA contractors, interns, or grantees who have been provided EPA email addresses and who have been identified as custodians of information that needs to be preserved in the anticipation of litigation. The records in the system will include these individuals' names and EPA email addresses which are entered into the system by designated EPA employees responsible for the administration of litigation holds. Information in the system includes litigation hold notices and answers to certification questions. Reports may be generated from the system that identify whether an individual is designated as a custodian of hold-responsive information, as well as reports containing the information received from individuals in response to questions asked through the litigation hold system.

- eDiscovery Case Tracking Files. The case tracking files contain information about the cases created in response to a litigation, investigation, FOIA matter or other formal information request. Case tracking files may contain the names, phone numbers, organizations, and email addresses of EPA employees and EPA contractors, interns, or grantees who have been identified as custodians in a case or as points of contact for managing the case. Information in the case tracking files may include the location of the information to be searched, search terms and case notes

entered into the system by designated EPA employees or contractors responsible for operating EPA's eDiscovery Enterprise Tool Suite.

- **eDiscovery Collection Files.** The collection files contain information potentially responsive to a litigation, investigation, FOIA matter or other formal information request. The Tool Suite may capture many types of personally identifiable information depending on where that information is stored, including an individual's name; work address and telephone number; home address and telephone number; email addresses; vehicle information; names of individuals associated with a FOIA request or litigation hold; or other related information. The collection files contain all data collected by the tools using the search criteria and may contain, but not be limited to, correspondence (e.g., case coordination reports; memoranda and other records of communication, including electronic communication over email systems or instant messaging among other EPA employees and/or personnel of other federal agencies and outside parties and attachments to those messages or communications); local/shared drive data; information collected or compiled from EPA database systems; spreadsheets of data collections often including personally identifiable information or law enforcement data used to track the process of investigations or focus investigative priorities; records relating to litigation by or against the United States government; records relating to requests for EPA records other than requests under the FOIA and the Privacy Act of 1974; legal documents including complaints, summaries, affidavits, litigation reports, motions, subpoenas and any other court filing or administrative filing, or other related litigation documents; documentary evidence; supporting documents related to the legal and programmatic issues of a case; transcripts of interviews; regulatory history (i.e., permits and reports generated as a result of normal program activity); administrative record material and comments on administrative records; technical support (reports generated to test search criteria); investigative notes; reports requesting permission and use; transcripts of tapes; records checks (personal history, police information, fingerprint cards, photographs); property reports; property obtained and retained by an examiner including documents, personal property and documentary or other evidence; employment records and information

related to employment matters; claims and records regarding discrimination, including employment and sex discrimination; personnel matters; contracts and information relating to contracts; manifests and other related investigative information.

RECORD SOURCE CATEGORIES:

EPA employees; employees of federal contractors; employees of other federal agencies and of state, local, tribal and foreign agencies; witnesses; informants; public source materials; and other persons who may have information relevant to the search criteria.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

EPA's General Routine Uses A, C, D, E, F, G, H, I, K, and L apply to this system. Please refer to <https://www.federalregister.gov/documents/2008/01/14/E8-445/amendment-to-general-routine-uses> for a full explanation of these routine uses (73 FR 2245).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in the system are stored in database applications running on computer servers.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Litigation hold and case tracking files are assigned a case file control number or case name. Information collected from individuals pertaining to particular cases may be retrieved by names of individuals, email addresses, and other unique identifiers.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records stored in the system are subject to records schedule 1012 and 0089.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Computer records are maintained in a secure, password protected computer system. Role-based access controls limit a user's access to the information in the system. Users are provided access to information in the system based on their need to know. Individuals working on a particular matter will be given access to the information related to that matter. The eDiscovery Enterprise Tool Suite is a password protected system requiring all users log in to access the information in the system. The system times out after a period of latency ensuring a user re-authenticates their session with a username and password. The system also maintains a user log that identifies

and records persons who access and use the system. Users of EPA systems are required to complete security and privacy training on an annual basis to ensure continued access to the system. All records are maintained in secure areas and buildings with physical access controls.

RECORD ACCESS PROCEDURES:

Request for access must be made in accordance with the procedures described in EPA's Privacy Act regulations at 40 CFR part 16. Requesters will be required to provide adequate identification, such as a driver's license, employee identification card or other identifying document. Additional identification procedures may be required in some instances.

CONTESTING RECORD PROCEDURES:

Requests for correction or amendment must identify the record to be changed and the corrective action sought. Complete EPA Privacy Act procedures are described in EPA's Privacy Act regulations at 40 CFR part 16.

NOTIFICATION PROCEDURES:

Any individual who wants to know whether this system of records contains a record about him or her should make a written request to the Agency Privacy Officer, MC 2831T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

For those records within the system collected and maintained pursuant to the Federal Rules of Civil Procedure (FRCP) and/or for the purpose of civil discovery, action or proceeding, 5 U.S.C. 552a(d)(5) will apply, stating that "nothing in this [Act] shall allow an individual access to any information compiled in reasonable anticipation of a civil action or proceeding." In addition, pursuant to 5 U.S.C. 552a(k)(2), this system is exempt from the following provisions of the Privacy Act, subject to the limitations set forth in that subsection: 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H) and (f)(2) through (5). Finally, pursuant to 5 U.S.C. 552a(j)(2), when records are contained in this system related to a criminal enforcement proceeding, this system is exempt from the following provisions of the Privacy Act, subject to the limitations set forth in that subsection: 5 U.S.C. 552a(c)(3), (c)(4), (d), (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(5), (e)(8), (f)(2) through (f)(5) and (g).

HISTORY:

None.

Dated: May 30, 2018.

Steven Fine,

Principal Deputy Assistant Administrator.

[FR Doc. 2018-16117 Filed 7-26-18; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[CG Docket No. 03-123; DA 18-733]

Notice of Certification of State Telecommunications Relay Services (TRS) Programs

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Federal Communications Commission's (FCC or Commission) Consumer and Governmental Affairs Bureau (Bureau) hereby grants renewals of certifications to the state and U.S. territory TRS programs listed below.

DATES: These certifications, conditioned on a demonstration of ongoing compliance with the Commission's rules governing TRS, shall remain in effect for a five (5) year period, beginning July 26, 2018, and ending July 25, 2023, pursuant to 47 CFR 64.606(c). Beginning one year prior to the expiration of these certifications, July 25, 2022, each state or U.S. territory may apply for renewal of its TRS program certification by filing documentation in accordance with the Commission's rules, pursuant to 47 CFR 64.606(a).

FOR FURTHER INFORMATION CONTACT: Dana Wilson, Consumer and Governmental Affairs Bureau at: (202) 418-2247; email: Dana.Wilson@fcc.gov.

SUPPLEMENTARY INFORMATION: The full text of this document and copies of the filed applications are available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portal II, 445 12th Street SW, Room CY-A257, Washington, DC 20554. Applications also may be found by searching on the Commission's Electronic Comment Filing System at: <http://apps.fcc.gov/ecfs/> (insert CG Docket No. 03-123 into the Proceeding block). This document can also be downloaded in Word and Portable Document Format (PDF) at <https://www.fcc.gov/general/disability-rights-office-headlines>.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the Consumer and Governmental Affairs Bureau at (202)

418-0530 (voice), (844) 432-2275 (videophone), or (202) 418-0432 (TTY).

Synopsis

After reviewing each of the state and U.S. territory applications received, the Bureau has determined that:

(1) The TRS programs of the listed states and U.S. territories meet or exceed all operational, technical, and functional minimum standards contained in § 64.604 of the Commission's rules;

(2) The TRS programs of the listed states and U.S. territories make available adequate procedures and remedies for enforcing the requirements of their state and U.S. territory programs; and

(3) The TRS programs of the listed states and U.S. territories in no way conflict with federal law.

The Bureau also has determined that, where applicable, the intrastate funding mechanisms of the listed states and U.S. territories are labeled in a manner that promotes national understanding of TRS and does not offend the public, consistent with § 64.606(d) of the Commission's rules.

STATES AND U.S. TERRITORIES APPROVED FOR CERTIFICATION

File No: TRS-46-17
Alabama Public Service Commission
State of Alabama
File No: TRS-19-17
Regulatory Commission of Alaska
State of Alaska
File No: TRS-47-17
Arkansas Deaf and Hearing Impaired Telecommunications Service Corporation
State of Arkansas
File No: TRS-02-17
Arizona Commission for the Deaf and Hard of Hearing
State of Arizona
File No: TRS-32-17
California Public Utilities Commission
State of California
File No: TRS-23-17
Colorado Public Utilities Commission
State of Colorado
File No: TRS-48-17
Connecticut Public Utilities Regulatory Authority
State of Connecticut
File No: TRS-35-17
Delaware Public Service Commission
State of Delaware
File No: TRS-49-17
Public Service Commission of the District of Columbia
District of Columbia
File No: TRS-50-17
Florida Public Service Commission
State of Florida
File No: TRS-51-17

Georgia Public Service Commission
State of Georgia
File No: TRS-22-17
Hawaii Public Utilities Commission
State of Hawaii
File No: TRS-43-17
Idaho Public Service Commission
State of Idaho
File No: TRS-10-17
Illinois Commerce Commission
State of Illinois
File No: TRS-08-17
Indiana Telephone Relay Access Corporation
State of Indiana
File No: TRS-03-17
Iowa Utilities Board
State of Iowa
File No: TRS-07-17
Kansas Dual Party Relay Services
State of Kansas
File No: TRS-52-17
Kentucky Public Service Commission
Commonwealth of Kentucky
File No: TRS-13-17
Louisiana Relay Administration Board
State of Louisiana
File No: TRS-53-17
Maine Telecommunications Relay Service Advisory Council
State of Maine
File No: TRS-33-17
Maryland Department of Information Technology Telecommunications Access of Maryland
State of Maryland
File No: TRS-34-17
Massachusetts Department of Telecommunications and Cable
Commonwealth of Massachusetts
File No: TRS-54-17
Michigan Public Service Commission
State of Michigan
File No: TRS-39-17
Minnesota Department of Commerce—Telecommunications Access Minnesota
State of Minnesota
File No: TRS-55-17
Mississippi Public Service Commission
State of Mississippi
File No: TRS-15-17
Missouri Public Service Commission
State of Missouri
File No: TRS-56-17
Montana Department of Public Health and Human Services
State of Montana
File No: TRS-40-17
Nebraska Public Service Commission
State of Nebraska
File No: TRS-25-17
Nevada Department of Health and Human Services Aging and Disability Services
State of Nevada
File No: TRS-42-17
New Hampshire Public Service

Commission
State of New Hampshire
File No: TRS-45-17
New Jersey Board of Public Utilities
State of New Jersey
File No: TRS-14-17
New Mexico Commission for the Deaf
and Hard of Hearing
State of New Mexico
File No: TRS-16-17
New York State Department of Public
Service
State of New York
File No: TRS-30-17
North Carolina Utilities Commission
State of North Carolina
File No: TRS-12-17
North Dakota Public Service
Commission
State of North Dakota
File No: TRS-37-17
Public Utilities Commission of Ohio
State of Ohio
File No: TRS-57-17
Oklahoma Telephone Association
State of Oklahoma
File No: TRS-36-17
Oregon Public Utility Commission
State of Oregon
File No: TRS-58-17
Pennsylvania Public Utility
Commission
Commonwealth of Pennsylvania
File No: TRS-28-17
Telecommunications Regulatory
Board of Puerto Rico
Puerto Rico
File No: TRS-59-17
Rhode Island Public Utilities
Commission
State of Rhode Island
File No: TRS-62-17
Micronesian Telephone Corporation
d/b/a Pacific Telecom, Inc.
Saipan
File No: TRS-11-17
South Carolina Public Service
Commission
State of South Carolina
File No: TRS-60-17
Public Service Commission of South
Dakota
State of South Dakota
File No: TRS-20-17
Tennessee Public Utility Commission
State of Tennessee
File No: TRS-17-17
Public Utility Commission of Texas
State of Texas
File No: TRS-61-17
Virgin Islands Public Service
Commission
U.S. Virgin Islands
File No: TRS-09-17

Utah Public Service Commission
State of Utah
File No: TRS-44-17
Vermont Department of Public
Service
State of Vermont
File No: TRS-04-17
Virginia Department for the Deaf and
Hard of Hearing
Commonwealth of Virginia
File No: TRS-27-17
Washington Department of Social and
Health Services
Office of the Deaf and Hard of Hearing
State of Washington
File No: TRS-06-17
Public Service Commission of West
Virginia
State of West Virginia
File No: TRS-01-17
Wisconsin Department of
Administration
Wisconsin Telecommunications Relay
Systems
State of Wisconsin
File No: TRS-18-17
Wyoming Department of Workforce
Services
Division of Vocational Rehabilitation
State of Wyoming

Federal Communications Commission.
Eliot Greenwald,
*Deputy Chief, Disability Rights Office,
Consumer and Governmental Affairs Bureau.*
[FR Doc. 2018-16041 Filed 7-26-18; 8:45 am]
BILLING CODE 6712-01-P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may

express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 13, 2018.

A. Federal Reserve Bank of St. Louis (David L. Hubbard, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166-2034. Comments can also be sent electronically to

Comments.applications@stls.frb.org:

1. *First State Bancorp, Inc., Caruthersville, Missouri*; to acquire 100 percent of the voting shares of Mississippi County Savings and Loan Association, Charleston, Missouri, and thereby engage in operating a savings association pursuant to section 225.28(b)(4)(ii).

Board of Governors of the Federal Reserve System, July 24, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018-16062 Filed 7-26-18; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

Granting of Requests for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination—on the dates indicated—of the waiting period provided by law and the premerger notification rules. The listing for each transaction includes the transaction number and the parties to the transaction. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

EARLY TERMINATIONS GRANTED—JUNE 1, 2018 THRU JUNE 30, 2018

06/01/2018

20181214	G	American Industrial Partners Capital Fund V, L.P.; Gene K. Ponder and Patsy K. Ponder; American Industrial Partners Capital Fund V, L.P.
20181277	G	Mr. Len Blavatnik; Opendoor Labs Inc.; Mr. Len Blavatnik.
20181284	G	Permira VI L.P. 1; WeddingWire, Inc.; Permira VI L.P. 1.

06/04/2018

20181236	G	JLL Partners Fund VII, L.P.; Integer Holdings Corporation; JLL Partners Fund VII, L.P.
20181237	G	Water Street Healthcare Partners III, L.P.; Integer Holdings Corporation; Water Street Healthcare Partners III, L.P.
20181305	G	Carl C. Icahn; AmTrust Financial Services, Inc.; Carl C. Icahn.
20181307	G	DIF Infrastructure V Cooperatief U.A.; Syncora Holdings Ltd.; DIF Infrastructure V Cooperatief U.A.
20181325	G	Monomoy Capital Partners III, L.P.; EMC Topco, Inc.; Monomoy Capital Partners III, L.P.
20181326	G	OCF Trust; New Mountain Partners IV Cayman (AIV-A), L.P.; OCF Trust.
20181330	G	AOT Building Products LP; Versatex Holdings, LLC; AOT Building Products LP.
20181331	G	TPG Growth IV, L.P.; Audax Private Equity Fund V-A, L.P.; TPG Growth IV, L.P.
20181333	G	Qingdao Haier Co., Ltd.; Haier Group Corporation; Qingdao Haier Co., Ltd.
20181338	G	BCP Energy Services Fund-A, LP; BCP Energy Services Fund, LP; BCP Energy Services Fund-A, LP.
20181339	G	ICG Europe Fund VII SCSp; MV Holding GmbH; ICG Europe Fund VII SCSp.
20181340	G	Charlesbank Equity Fund IX, Limited; Rockport Blocker, LLC; Charlesbank Equity Fund IX, Limited.
20181341	G	The Goldman Sachs Group, Inc.; Vail Holdco Corp.; The Goldman Sachs Group, Inc.
20181342	G	VWR Partners, L.P.; Vail Holdco Corp.; VWR Partners, L.P.
20181343	G	Wafra Cornerstone Partners L.P.; The Weinstein Company Holdings LLC; Wafra Cornerstone Partners L.P.
20181345	G	Aretex Capital Partners Fund, LP; Gabriel Hammond; Aretex Capital Partners Fund, LP.
20181357	G	Madison Dearborn Capital Partners VII-A, L.P.; Aurora Resurgence Fund II L.P.; Madison Dearborn Capital Partners VII-A, L.P.

06/05/2018

20180022	G	Northrop Grumman Corporation; Orbital ATK, Inc.; Northrop Grumman Corporation.
20181261	G	Vivus, Inc.; Johnson & Johnson; Vivus, Inc.
20181344	G	ArcLight Energy Partners Fund VI, L.P.; Enbridge, Inc.; ArcLight Energy Partners Fund VI, L.P.
20181365	G	Keyera Corp.; Texon Holding II L.P.; Keyera Corp.

06/06/2018

20181275	G	Johnson & Johnson; HC2 Holdings, Inc.; Johnson & Johnson.
20181354	G	The Cranemere Group Limited; TPG Growth II DE AIV II, L.P.; The Cranemere Group Limited.
20181355	G	HCA Healthcare, Inc.; North Cypress Medical Center Operation Company, LTD; HCA Healthcare, Inc.
20181359	G	Arkoma Drilling, L.P.; Comstock Resources, Inc.; Arkoma Drilling, L.P.
20181360	G	Williston Drilling, L.P.; Comstock Resources, Inc.; Williston Drilling, L.P.
20181366	G	DC Capital Partners Fund II, L.P.; Thomas J. Campbell; DC Capital Partners Fund II, L.P.
20181367	G	Berwind Holding Corp.; Bertram Growth Capital II, L.P.; Berwind Holding Corp.
20181369	G	Thomas J. Campbell; DC Capital Partners Fund II, L.P.; Thomas J. Campbell.
20181371	G	Adobe Systems Incorporated; Permira V L.P. 2; Adobe Systems Incorporated.

06/07/2018

20181332	G	Continental AG; OSRAM Licht AG; Continental AG.
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06/08/2018

20181308	G	Bank of Montreal; KGS Holdings, L.P.; Bank of Montreal.
20181328	G	R2G Foundation; First Quality Nonwovens, Inc.; R2G Foundation.
20181346	G	The Middleby Corporation; United Technologies Corporation; The Middleby Corporation.
20181352	G	Colliers International Group Inc.; Harrison Street Real Estate Capital LLC; Colliers International Group Inc.
20181373	G	Conifex Timber Inc.; BW SLC AIV III L.P.; Conifex Timber Inc.
20181376	G	Steel Dynamics, Inc.; Rio Purus Participacoes S/A; Steel Dynamics, Inc.
20181380	G	David A. Tepper; Carolina PSLFC, LLC; David A. Tepper.
20181401	G	EQT Mid Market US Limited Partnership; Arlington Capital Partners II, L.P.; EQT Mid Market US Limited Partnership.
20181403	G	Anthem, Inc.; Aspire Health, Inc.; Anthem, Inc.

06/12/2018

20181351	G	PS Holdings Independent Trust; Lowe's Companies, Inc.; PS Holdings Independent Trust.
20181400	G	American Family Insurance Mutual Holding Company; Main Street America Group Mutual Holdings, Inc.; American Family Insurance Mutual Holding Company.
20181402	G	Elon Musk; Tesla, Inc.; Elon Musk.
20181410	G	Cornell Capital Partners III LP; AMCP AIV, L.P.; Cornell Capital Partners III LP.
20181415	G	The Kroger Co.; Relish Labs LLC; The Kroger Co.

EARLY TERMINATIONS GRANTED—JUNE 1, 2018 THRU JUNE 30, 2018—Continued

06/15/2018

20181348	G	TransUnion; iovation, Inc.; TransUnion.
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06/19/2018

20181246	G	HS Spinco, Inc.; Direct Vet Marketing, Inc.; HS Spinco, Inc.
20181316	G	Carl C. Icahn; Dell Technologies Inc.; Carl C. Icahn.
20181317	G	Carl C. Icahn; Dell Technologies Inc.; Carl C. Icahn.
20181319	G	The CVRF Trust; Dell Technologies Inc.; The CVRF Trust.
20181323	G	Carl C. Icahn; Energen Corporation; Carl C. Icahn.
20181392	G	Bain Capital Fund XII, L.P.; Palermo TT Holdings, Inc.; Bain Capital Fund XII, L.P.
20181404	G	EQT Corporation; Rice Midstream Partners LP; EQT Corporation.
20181409	G	GC EOS InvestCo, LLC; Letterone Investment Holdings S.A.; GC EOS InvestCo, LLC.
20181416	G	Vista Equity Partners Fund VI, L.P.; Integral Ad Science, Inc.; Vista Equity Partners Fund VI, L.P.
20181420	G	Windjammer Senior Equity Fund IV, L.P.; EXT Acquisitions, Inc.; Windjammer Senior Equity Fund IV, L.P.
20181424	G	The Resolute Fund IV, L.P.; GlobalTranz Enterprises, Inc.; The Resolute Fund IV, L.P.
20181425	G	ABRY Senior Equity V, L.P.; SV Holdco, LLC; ABRY Senior Equity V, L.P.
20181427	G	Kelso Investment Associates IX, L.P.; Michael A. DiMayo; Kelso Investment Associates IX, L.P.
20181428	G	Kelso Investment Associates IX, L.P.; Kevin E. Myers; Kelso Investment Associates IX, L.P.
20181429	G	Grammer AG; Industrial Opportunity Partners, L.P.; Grammer AG.
20181432	G	Superior Plus Corp.; NGL Energy Partners LP; Superior Plus Corp.
20181437	G	Mrs. Wu Bifeng; Industrial Opportunity Partners, L.P.; Mrs. Wu Bifeng.
20181438	G	Polaris Industries Inc.; Boat Holdings, LLC; Polaris Industries Inc.
20181439	G	Fresenius Medical Care AG & Co. KGaA; Humacyte, Inc.; Fresenius Medical Care AG & Co. KGaA.
20181444	G	Wynnchurch Capital Partners IV, L.P.; Sequel Industrial Products Holdings, LLC; Wynnchurch Capital Partners IV, L.P.
20181447	G	Partners Group Access 967 L.P.; AI Global Investments & Cy S.C.A.; Partners Group Access 967 L.P.

06/20/2018

20181378	G	Grand Canyon University Foundation; Grand Canyon Education, Inc.; Grand Canyon University Foundation.
20181398	G	Axiom Infrastructure NA IV L.P.; EIF United States Power Fund IV, L.P.; Axiom Infrastructure NA IV L.P.
20181423	G	Spirit RR Holdings, Inc.; Reorg Research, Inc.; Spirit RR Holdings, Inc.
20181434	G	WellCare Health Plans, Inc.; Dr. David Cotton and Shery Cotton; WellCare Health Plans, Inc.
20181436	G	Mrs. Wu Bifeng; Grammer AG; Mrs. Wu Bifeng.

06/21/2018

20181334	G	BBA Aviation plc; Downstream Aviation, LP; BBA Aviation plc.
20181408	G	Thoma Bravo Fund XII, L.P.; LogRhythm, Inc.; Thoma Bravo Fund XII, L.P.

06/22/2018

20181364	G	Eurazeo S.E.; Polycarbon Industries, Inc.; Eurazeo S.E.
20181450	G	KKR Americas Fund XII, L.P.; Boxer Parent Company Inc.; KKR Americas Fund XII, L.P.
20181454	G	Spectrum Equity VII, L.P.; Lucid Software Inc.; Spectrum Equity VII, L.P.
20181458	G	Capgemini SE; Leidos Holdings, Inc.; Capgemini SE.
20181460	G	Arlington Capital Partners IV, L.P.; Julian A. Guerra; Arlington Capital Partners IV, L.P.
20181461	G	Hexagon AB; Robert D. Hambrick; Hexagon AB.
20181462	G	Oak Hill Capital Partners IV (Onshore), L.P.; VetCor Investment Holdings, L.P.; Oak Hill Capital Partners IV (Onshore), L.P.
20181463	G	H.I.G. Capital Partners V, L.P.; Galaxy Invest Inc.; H.I.G. Capital Partners V, L.P.
20181472	G	KSLB Group Holdings, LLC; Tyson Family 2009 Trust; KSLB Group Holdings, LLC.
20181474	G	Qurate Retail, Inc.; Marriott Vacations Worldwide Corporation; Qurate Retail, Inc.
20181475	G	Audax Private Equity Fund V-A, L.P.; Riverside Capital Appreciation Fund V, L.P.; Audax Private Equity Fund V-A, L.P.
20181484	G	RYPS, LLC; Conserve School Trust; RYPS, LLC.
20181486	G	Seidler Equity Partners VI, L.P.; Newell Brands Inc.; Seidler Equity Partners VI, L.P.
20181488	G	Primavera Capital Partners III L.P.; Zoox, Inc.; Primavera Capital Partners III L.P.
20181493	G	OCP Trust; Water Street Healthcare Partners III, L.P.; OCP Trust.
20181494	G	Golden Gate Capital Opportunity Fund, L.P.; Wells Fargo & Company; Golden Gate Capital Opportunity Fund, L.P.
20181497	G	Aurora Equity Partners V L.P.; Arsenal Capital Partners QP II LP; Aurora Equity Partners V L.P.

06/26/2018

20181449	G	Intercontinental Exchange, Inc.; TheDebtCenter, LLC; Intercontinental Exchange, Inc.
20181483	G	Osprey Energy Acquisition Corp.; Royal Resources L.P.; Osprey Energy Acquisition Corp.
20181492	G	Titan DI Holdings, Inc.; Drilling Info Holdings, Inc.; Titan DI Holdings, Inc.
20181502	G	CenterPoint Energy, Inc.; Vectren Corporation; CenterPoint Energy, Inc.

06/27/2018

20181473	G	GCI Liberty, Inc.; LendingTree, Inc.; GCI Liberty, Inc.
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06/28/2018

20181452	G	Elliott Associates, L.P.; Sempra Energy; Elliott Associates, L.P.
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EARLY TERMINATIONS GRANTED—JUNE 1, 2018 THRU JUNE 30, 2018—Continued

20181453	G	Elliott International Limited; Sempra Energy; Elliott International Limited.
20181455	G	JSW Energy Interests LP; Sempra Energy; JSW Energy Interests LP.

06/29/2018

20181211	G	American Well Corporation; Avizia, Inc.; American Well Corporation.
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FOR FURTHER INFORMATION CONTACT:

Theresa Kingsberry, Program Support Specialist, Federal Trade Commission Premerger Notification Office, Bureau of Competition, Room CC-5301, Washington, DC 20024, (202) 326-3100.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 2018-16025 Filed 7-26-18; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC)**

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of closed meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC).

DATES: The meeting will be held on August 14, 2018, 1:00 p.m. to 3:00 p.m., EDT (CLOSED).

ADDRESSES: Teleconference.

FOR FURTHER INFORMATION CONTACT:

Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F-63, Atlanta, GA 30341, Telephone (770) 488-1430, Email address: NCIPCBSC@cdc.gov.

SUPPLEMENTARY INFORMATION: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Purpose: The Board of Scientific Counselors makes recommendations regarding policies, strategies, objectives, and priorities; and reviews progress toward injury prevention goals and

provides evidence in injury prevention-related research and programs. The Board also provides advice on the appropriate balance of intramural and extramural research, the structure, progress and performance of intramural programs. The Board is designed to provide guidance on extramural scientific program matters, including the: (1) Review of extramural research concepts for funding opportunity announcements; (2) conduct of Secondary Peer Review of extramural research grants, cooperative agreements, and contracts applications received in response to the funding opportunity announcements as it relates to the Center's programmatic balance and mission; (3) submission of secondary review recommendations to the Center Director of applications to be considered for funding support; (4) review of research portfolios, and (5) review of program proposals.

Matters To Be Considered: The agenda will include discussions on Secondary Peer Review of extramural research grant and cooperative agreement applications received in response to one (1) Notice of Funding Opportunity (NOFO): RFA-CE-18-006, Research Grants for Primary or Secondary Prevention of Opioid Overdose (RO1). Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dia Taylor,

Acting Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2018-16101 Filed 7-26-18; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****National Center for Health Statistics (NCHS), ICD-10 Coordination and Maintenance (C&M) Committee Meeting**

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The CDC, National Center for Health Statistics (NCHS), Classifications and Public Health Data Standards Staff, announces the following meeting of the ICD-10 Coordination and Maintenance (C&M) Committee meeting. This meeting is open to the public, limited only by the space available. The meeting room accommodates approximately 240 people. We will be broadcasting the meeting live via Webcast at <http://www.cms.gov/live/>.

DATES: The meeting will be held on September 11, 2018, 9:00 a.m. to 5:00 p.m. EDT and September 12, 2018, 9:00 a.m. to 5:00 p.m. EDT.

ADDRESSES: Centers for Medicare and Medicaid Services (CMS) Auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT:

Traci Ramirez, Program Specialist, CDC, 3311 Toledo Rd., Hyattsville, MD 20782 telephone (301) 458-4454; email address TRamirez@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The ICD-10 Coordination and Maintenance (C&M) Committee is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Tenth Revision, Clinical Modification and ICD-10 Procedure Coding System.

Matters To Be Considered: The agenda will include discussions on ICD-10-PCS Topics:

Intraoperative Fluorescence Vascular Angiography for Lymphatic Mapping in Cervical and Uterine Cancers
Insertion of Intramedullary Nail Limb Lengthening System
Cell Suspension Autografting—REPEAT Subcutaneous Implantable Defibrillator System

Administration of erdafitinib
Administration of esketamine
hydrochloride nasal spray, for
intranasal use
Administration of ERLEADATM
(apalutamide), for oral use

Addenda and Key Updates

ICD-10-CM Topics
Deep Vein Thrombosis
Dravet Syndrome
Latent Tuberculosis Infection
Pressure ulcer of mucosal membrane by
site
ICD-10-CM Addendum

Agenda items are subject to change as priorities dictate.

Security Considerations: Due to increased security requirements, CMS has instituted stringent procedures for entrance into the building by non-government employees.

Attendees will need to present valid government-issued picture identification, and sign-in at the security desk upon entering the building.

Attendees who wish to attend the September 11-12, 2018, ICD-10-CM C&M meeting must submit their name and organization by September 3, 2018, for inclusion on the visitor list. This visitor list will be maintained at the front desk of the CMS building and used by the guards to admit visitors to the meeting.

Participants who attended previous Coordination and Maintenance meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you wish attend.

Please register to attend the meeting on-line at: <http://www.cms.hhs.gov/apps/events/>.

Please contact Mady Hue (410-786-4510) or Marilu.hue@cms.hhs.gov for questions about the registration process.

Note: CMS and NCHS no longer provide paper copies of handouts for the meeting. Electronic copies of all meeting materials will be posted on the CMS and NCHS websites prior to the meeting at <http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03meetings.asp#TopOfPage> and https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention, and the Agency for Toxic Substances and Disease Registry.

Dia Taylor,

Acting Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2018-16102 Filed 7-26-18; 8:45 am]

BILLING CODE 4160-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-18-0556]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Assisted Reproductive Technology (ART) Program Reporting System to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on May 10, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy

of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Assisted Reproductive Technology (ART) Program Reporting System (OMB No. 0920-0556, expires 7/31/2018)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 2(a) of Public Law 102-493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), 42 U.S.C. 263a-1(a)) requires that each assisted reproductive technology (ART) program shall annually report to the Secretary through the Centers for Disease Control and Prevention: (1) Pregnancy success rates achieved by such ART program, and (2) the identity of each embryo laboratory used by such ART program and whether the laboratory is certified or has applied for such certification under the Act. The required information is currently reported by ART programs to CDC as specified in the Assisted Reproductive Technology (ART) Program Reporting System (OMB No. 0920-0556, exp. 7/31/2018). CDC seeks to extend OMB approval for a period of three years. The revised total burden estimate is lower than under the previous approval, due to removal of the burden associated with a one-time system upgrade that was completed under the prior approval. However, some of this burden reduction will be offset by an increase in the number of ART clinics and cycles reported, due to an increase in the utilization of ART in the United States.

The currently approved program reporting system, also known as the National ART Surveillance System (NASS), includes information about all ART cycles initiated by any of the ART programs in the United States. An ART cycle is considered to begin when a woman begins taking ovarian stimulatory drugs or starts ovarian monitoring with the intent of having embryos transferred; for each cycle, CDC collects information about the pregnancy outcome, as well as a number of data items deemed by experts in the field to be important to explain

variability in success rates across ART programs and individuals.

Each ART program reports its annual ART cycle data to CDC in mid-December. The annual data reporting consists of information about all ART cycles that were initiated in the previous calendar year. For example, the December 2017 reports described ART cycles that were initiated between January 1, 2016, and December 31, 2016. Data elements and definitions currently in use reflect CDC's prior consultations with representatives of the Society for Assisted Reproductive Technology (SART), the American Society for Reproductive Medicine, and RESOLVE: The National Infertility Association (a national, nonprofit consumer

organization), as well as a variety of individuals with expertise and interest in this field.

The estimated number of respondents (ART programs or clinics) is 464, based on the number of clinics that provided information in 2015; the estimated average number of responses (ART cycles) per respondent is 350. Additionally, approximately 5–10% of responding clinics will be randomly selected each year to participate in data validation and quality control activities; an estimated 35 clinics will be selected to report validation data on 70 cycles each on average. Finally, respondents may provide feedback to CDC about the usability and utility of the reporting system. The option to participate in the

feedback survey is presented to respondents when they complete their required data submission. Participation in the feedback survey is voluntary and is not required by the FCSRCA. CDC estimates that 75% of ART programs will participate in the feedback survey.

The collection of ART cycle information allows CDC to publish an annual report to Congress as specified by the FCSRCA and to provide information needed by consumers. OMB approval is requested for three years. The estimated annualized Burden Hours are 114,631 which is a decrease of 1,794 from the current OMB-approved collection. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
ART Clinics	NASS	464	350	42/60
	Data Validation	35	70	23/60
	Feedback Survey	348	1	2/60

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018-16091 Filed 7-26-18; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-18-0222]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER), to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on March 1, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30

days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions

regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB Control Number 0920-0222, Expiration 07/31/2018)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall undertake and support (by grant or contract) research, demonstrations, and evaluations respecting new or improved methods for obtaining current data to support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

The Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) is the focal point within NCHS for questionnaire and survey development, pre-testing, and evaluation activities for CDC surveys (such as the NCHS National Health

Interview Survey, OMB No. 0920–0214) and other federally sponsored surveys. NCHS is requesting 3 years of OMB Clearance for this generic submission.

The CCQDER and other NCHS programs conduct cognitive interviews, focus groups, in-depth or ethnographic interviews, usability tests, field tests/pilot interviews, and experimental research in laboratory and field settings, both for applied questionnaire development and evaluation as well as more basic research on measurement errors and survey response.

Various techniques to evaluate interviewer administered, self-administered, telephone, Computer Assisted Personal Interviewing (CAPI), Computer Assisted Self-Interviewing (CASI), Audio Computer-Assisted Self-Interviewing (ACASI), and web-based questionnaires are used.

The most common questionnaire evaluation method is the cognitive interview. These evaluations are conducted by the CCQDER and contractors, as needed. The interview structure consists of respondents first answering a draft survey question and then providing textual information to reveal the processes involved in answering the test question. Specifically, cognitive interview respondents are asked to describe how and why they answered the question as they did. Through the interviewing process, various types of question-response problems that would not normally be identified in a traditional survey interview, such as interpretive errors and recall accuracy, are uncovered. By conducting a comparative analysis of cognitive interviews, it is also possible to determine whether particular interpretive patterns occur within particular sub-groups of the population.

Interviews are generally conducted in small rounds totaling 40–100 interviews; ideally, the questionnaire is re-worked between rounds, and revisions are tested iteratively until interviews yield relatively few new insights.

Cognitive interviewing is inexpensive and provides useful data on questionnaire performance while minimizing respondent burden. Cognitive interviewing offers a detailed depiction of meanings and processes used by respondents to answer questions—processes that ultimately produce the survey data. As such, the method offers an insight that can transform understanding of question validity and response error. Documented findings from these studies represent tangible evidence of how the question performs. Such documentation also serves CDC data users, allowing them to be critical users in their approach and application of the data.

In addition to cognitive interviewing, a number of other qualitative and quantitative methods are used to investigate and research measurement error and the survey response process. These methods include conducting focus groups, usability tests, in-depth or ethnographic interviews, and the administration and analysis of questions in both representative and non-representative field tests. Focus groups are conducted by the CCQDER and contractors, as needed. They are group discussions whose primary purpose is to elicit the basic sociocultural understandings and terminology that form the basis of questionnaire design. Each group typically consists of one moderator and 4 to 10 participants, depending on the research question. In-depth or ethnographic interviews are one-on-one interviews designed to elicit

the understandings or terminology that are necessary for question design, as well as to gather detailed information that can contribute to the analysis of both qualitative and quantitative data. Usability tests are typically one-on-one interviews that are used to determine how a given survey or information collection tool functions in the field, and how the mode and layout of the instrument itself may contribute to survey response error and the survey response process.

In addition to these qualitative methods, NCHS also uses various tools to obtain quantitative data, which can be analyzed alone or analyzed alongside qualitative data to give a much fuller accounting of the survey response process. For instance, phone, internet, mail, and in-person follow-up interviews of previous NCHS survey respondents may be used to test the validity of survey questions and questionnaires and to obtain more detailed information that cannot be gathered on the original survey. Additionally, field or pilot tests may be conducted on both representative and non-representative samples, including those obtained from commercial survey and web panel vendors. Beyond looking at traditional measures of survey errors (such as item missing and non-response rates, and response latency), these pilot tests can be used to run experimental designs in order to capture how different questions function in a field setting.

Similar methodology has been adopted by other federal agencies, as well as by academic and commercial survey organizations. There are no costs to respondents other than their time. The total estimated annual burden hours are 7,783.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals or households	Eligibility Screening	4,000	1	5/60
Individuals or households	Questionnaire Development Studies	7,300	1	55/60
Individuals or households	Respondent Data Collection Sheet	7,300	1	5/60
Individuals or households	Focus groups	100	1	90/60

Jeffery M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018-16090 Filed 7-26-18; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Health Disparities Subcommittee (HDS)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Advisory Committee to the Director, Centers for Disease Control and Prevention—Health Disparities Subcommittee (ACD, CDC—HDS). This meeting is open to the public, limited only by the 50 audio phone lines. The public is also welcome to listen to the meeting by teleconference. Please dial (866) 918-8397 and enter code 9346283. There are 50 lines available. The public comment period is from 3:15 p.m.–3:20 p.m.

DATES: The meeting will be held on October 9, 2018, 1:30 p.m. to 3:30 p.m., EDT.

ADDRESSES: Teleconference phone (866) 918-8397 and enter code 9346283.

FOR FURTHER INFORMATION CONTACT: Leandris Liburd, Ph.D., M.P.H., M.A., Designated Federal Officer, Health Disparities Subcommittee, Advisory Committee to the Director, CDC, 1600 Clifton Road NE, M/S K-77, Atlanta, Georgia 30329. Telephone (404) 498-6482; Email: ACDDirector@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The Subcommittee will provide counsel to the CDC Director through the ACD on strategic and other health disparities and health equity issues and provide guidance on opportunities for CDC.

Matters to be Considered: The agenda will include discussions on new member orientation. This meeting will provide information to new members regarding their role & duties on this subcommittee. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated

the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dia Taylor,

Acting Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2018-16103 Filed 7-26-18; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-P-1283]

Determination That Metaxalone Tablets, 640 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that metaxalone tablets, 640 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for metaxalone tablets, 640 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Glen Cheng, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6217, Silver Spring, MD 20993-0002, 301-796-1494.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Metaxalone tablets, 640 mg, are the subject of NDA 22-503, held by Primus Pharmaceuticals, Inc., and initially approved on June 1, 2015. Metaxalone tablets, 640 mg, are indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.

In a letter dated September 30, 2015, the previous NDA holder CorePharma, LLC notified FDA that metaxalone tablets, 640 mg, were discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Sovereign Pharmaceuticals, LLC submitted a citizen petition dated March 26, 2018 (Docket No. FDA-2018-P-1283), under 21 CFR 10.30, requesting that the Agency determine whether metaxalone tablets, 640 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that metaxalone tablets, 640 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that metaxalone tablets, 640 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of metaxalone tablets, 640 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was

not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list metaxalone tablets, 640 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to metaxalone tablets, 640 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16031 Filed 7–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Generic Drug User Fee Rates for Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II), authorizes the Food and Drug Administration (FDA, Agency, or we) to

assess and collect fees for abbreviated new drug applications (ANDAs), drug master files (DMFs), generic drug active pharmaceutical ingredient (API) facilities, finished dosage form (FDF) facilities, contract manufacturing organization (CMO) facilities, and generic drug applicant program user fees. In this document, FDA is announcing fiscal year (FY) 2019 rates for GDUFA II fees.

FOR FURTHER INFORMATION CONTACT:

Melissa Hurley, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202J, Silver Spring, MD 20993–0002, 240–402–4585.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j–41 and 379j–42) establish fees associated with human generic drug products. Fees are assessed on: (1) Certain types of applications for human generic drug products; (2) certain facilities where APIs and FDFs are produced; (3) certain DMFs associated with human generic drug products; and (4) generic drug applicants who have approved ANDAs (the program fee) (see section 744B(a)(2)–(5) of the FD&C Act).

GDUFA II stipulates that user fees should total \$493,600,000 annually adjusted each year for inflation. For FY 2019, the generic drug fee rates are: ANDA (\$178,799), DMF (\$55,013), domestic API facility (\$44,226), foreign API facility (\$59,226), domestic FDF facility (\$211,305), foreign FDF facility (\$226,305), domestic CMO facility (\$70,435), foreign CMO facility (\$85,435), large size operation generic drug applicant program (\$1,862,167), medium size operation generic drug

applicant program (\$744,867), and small business generic drug applicant program (\$186,217). These fees are effective on October 1, 2018, and will remain in effect through September 30, 2019.

II. Fee Revenue Amount for FY 2019

The base revenue amount for FY 2019 is \$493,600,000, as set in the statute (see section 744B(b)(1) of the FD&C Act). GDUFA II directs FDA to use the yearly revenue amount as a starting point to set the fee rates for each fee type. For more information about GDUFA II, please refer to the FDA website (<https://www.fda.gov/gdufa>). The ANDA, DMF, API facility, FDF facility, CMO facility, and generic drug applicant program fee (GDUFA program fee) calculations for FY 2019 are described in this document.

GDUFA II specifies that the \$493,600,000 is to be adjusted for inflation increases for FY 2019 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see sections 744B(c)(1)(B) and (C) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of human generic drug activities for the first 3 of the preceding 4 fiscal years (see section 744B(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and total FTE for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2019. The 3-year average is 2.4152 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal year	2015	2016	2017	3-Year average
Total PC&B	\$2,232,304,000	\$2,414,728,159	\$2,581,551,000
Total FTE	15,484	16,381	17,022
PC&B per FTE	\$144,168	\$147,408	\$151,660
Percent Change from Previous Year	2.1136	2.2474	2.8845	2.4152

The statute specifies that this 2.4152 percent should be multiplied by the proportion of PC&B expended for

human generic drug activities for the first 3 of the preceding 4 fiscal years. Table 2 shows the amount of PC&B and

the total amount obligated for human generic drug activities from FY 2015 through FY 2017.

TABLE 2—PC&B AS A PERCENT OF FEE REVENUES SPENT ON THE PROCESS OF HUMAN GENERIC DRUG APPLICATIONS OVER THE LAST 3 YEARS

Fiscal year	2015	2016	2017	3-Year average
PC&B	\$201,116,305	\$242,963,571	\$271,748,229
Non-PC&B	\$251,589,013	\$250,987,599	\$262,058,852
Total Costs	\$452,705,318	\$493,951,170	\$533,807,081

TABLE 2—PC&B AS A PERCENT OF FEE REVENUES SPENT ON THE PROCESS OF HUMAN GENERIC DRUG APPLICATIONS OVER THE LAST 3 YEARS—Continued

Fiscal year	2015	2016	2017	3-Year average
PC&B Percent	44.4254	49.1878	50.9076	48.1736
Non-PC&B Percent	55.5746	50.8122	49.0924	51.8264

The payroll adjustment is 2.4152 percent multiplied by 48.1736 percent (or 1.1635 percent).

The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2019 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-

Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of human generic drug activities (see section 744B(c)(1)(C) of the FD&C Act). Table 3 provides the

summary data for the percent change in the specified CPI. The data are published by the Bureau of Labor Statistics and can be found on its website at: https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURA311SA0,CUUSA311SA0.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR BALTIMORE-WASHINGTON AREA

Year	2015	2016	2017	3-Year average
Annual CPI	155.353	157.180	159.202
Annual Percent Change	0.3268	1.1760	1.2864	0.9297

To calculate the inflation adjustment for non-pay costs, we multiply the 3-year average percent change in the CPI (0.9297 percent) by the proportion of all costs other than PC&B to total costs of human generic drug activities obligated. Because 48.1736 percent was obligated for PC&B as shown in table 2, 51.8264 percent is the portion of costs other than PC&B. The non-pay adjustment is 0.9297 percent times 51.8264 percent, or 0.4818 percent.

To complete the inflation adjustment for FY 2019, we add the PC&B component (1.1635 percent) to the non-PC&B component (0.4818 percent) for a total inflation adjustment of 1.6453 percent (rounded), making 1.016453. We then multiply the base revenue amount for FY 2019 (\$493,600,000) by 1.016453, yielding an inflation-adjusted amount of \$501,721,000 (rounded to the nearest thousand dollars).

III. ANDA Filing Fee

Under GDUFA II, the FY 2019 ANDA filing fee is owed by each applicant that submits an ANDA on or after October 1, 2018. This fee is due on the submission date of the ANDA. Section 744B(b)(2)(B) of the FD&C Act specifies that the ANDA fee will make up 33 percent of the \$501,721,000, which is \$165,567,930.

To calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2019. The submissions are broken down into three categories: New originals (submissions that have not been received by FDA previously); submissions that have been refused to

receive (RTR) for reasons other than failure to pay fees; and applications that are resubmitted after having been RTR for reasons other than failure to pay fees. An ANDA counts as one FAE; however, 75 percent of the fee paid for an ANDA that has been RTR shall be refunded according to GDUFA II if (1) the ANDA is refused for a cause other than failure to pay fees, or (2) the ANDA has been withdrawn prior to receipt (section 744B(a)(2)(D)(i) of the FD&C Act). Therefore, an ANDA that is considered not to have been received by FDA due to reasons other than failure to pay fees or withdrawn prior to receipt counts as one-fourth of an FAE. After an ANDA has been RTR, the applicant has the option of resubmitting. For user fee purposes, these resubmissions are equivalent to new original submissions—ANDA resubmissions are charged the full amount for an application (one FAE).

FDA utilized data from ANDAs submitted from October 1, 2013, to April 30, 2018, to estimate the number of new original ANDAs that will incur filing fees in FY 2019. For FY 2019, the Agency estimates that approximately 918 new original ANDAs will be submitted and incur filing fees. Not all of the new original ANDAs will be received by the Agency and some of those not received will be resubmitted in the same fiscal year. Therefore, the Agency expects that the FAE count for ANDAs will be 926 for FY 2019.

The FY 2019 application fee is estimated by dividing the number of FAEs that will pay the fee in FY 2019 (926) into the fee revenue amount to be

derived from ANDA application fees in FY 2019 (\$165,567,930). The result, rounded to the nearest dollar, is a fee of \$178,799 per ANDA.

The statute provides that those ANDAs that include information about the production of active pharmaceutical ingredients other than by reference to a DMF will pay an additional fee that is based on the number of such active pharmaceutical ingredients and the number of facilities proposed to produce those ingredients (see section 744B(a)(3)(F) of the FD&C Act). FDA considers that this additional fee is unlikely to be assessed often; therefore, FDA has not included projections concerning the amount of this fee in calculating the fees for ANDAs.

IV. DMF Fee

Under GDUFA II, the DMF fee is owed by each person that owns a type II active pharmaceutical ingredient DMF that is referenced, on or after October 1, 2012, in a generic drug submission by an initial letter of authorization. This is a one-time fee for each DMF. This fee is due on the earlier of the date on which the first generic drug submission is submitted that references the associated DMF or the date on which the drug master file holder requests the initial completeness assessment. Under section 744B(a)(2)(D)(iii) of the FD&C Act, if a DMF has successfully undergone an initial completeness assessment and the fee is paid, the DMF will be placed on a publicly available list documenting DMFs available for reference.

To calculate the DMF fee, FDA assessed the volume of DMF

submissions over time. The Agency assessed DMFs from October 1, 2016, to April 30, 2018, and concluded that averaging the number of fee-paying DMFs provided the most accurate model for predicting fee-paying DMFs for FY 2019. The monthly average of paid DMF submissions the Agency received in FY 2017 and FY 2018 is 38. To determine the FY 2019 projected number of fee-paying DMFs, the average of 38 DMF submissions is multiplied by 12 months, which results in 456 estimated FY 2019 fee-paying DMFs. FDA is estimating 456 fee-paying DMFs for FY 2019.

The FY 2019 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2019. Section 744B(b)(2)(A) of the FD&C Act specifies that the DMF fees will make up 5 percent of the \$501,721,000, which is \$25,086,050. Dividing the DMF revenue amount (\$25,086,050) by the estimated fee-paying DMFs (456), and rounding to the nearest dollar, yields a DMF fee of \$55,013 for FY 2019.

V. Foreign Facility Fee Differential

Under GDUFA II, the fee for a facility located outside the United States and its territories and possessions shall be \$15,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions. The basis for this differential is the extra cost incurred by conducting an inspection outside the United States and its territories and possessions.

VI. FDF and CMO Facility Fees

Under GDUFA II, the annual FDF facility fee is owed by each person who owns an FDF facility that is identified in at least one approved generic drug submission owned by that person or his affiliates. The CMO facility fee is owed by each person who owns an FDF facility that is identified in at least one approved ANDA but is not identified in an approved ANDA held by the owner of that facility or its affiliates. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(C) of the FD&C Act specifies that the FDF and CMO facility fee revenue will make up 20 percent of the \$501,721,000, which is \$100,344,200.

To calculate the fees, data from FDA's Integrity Services (IS) were utilized as the primary source of facility information for determining the denominators of each facility fee type. IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved

generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as FDF manufacturers in at least one approved generic drug submission. Based on FDA's IS data, the FDF and CMO facility denominators are 180 FDF domestic, 216 FDF foreign, 73 CMO domestic, and 97 CMO foreign facilities for FY 2019.

GDUFA II specifies that the CMO facility fee is to be equal to one-third the amount of the FDF facility fee. Therefore, to generate the target collection revenue amount from FDF and CMO facility fees (\$100,344,200), FDA must weight a CMO facility as one-third of an FDF facility. FDA set fees based on the estimate of 180 FDF domestic, 216 FDF foreign, 24.33 CMO domestic (73 multiplied by one-third), and 32.33 CMO foreign facilities (97 multiplied by one-third), which equals 452.66 total weighted FDF and CMO facilities for FY 2019.

To calculate the fee for domestic facilities, FDA first determines the total fee revenue that will result from the foreign facility differential by subtracting the fee revenue resulting from the foreign facility fee differential from the target collection revenue amount (\$100,344,200) as follows. The foreign facility fee differential revenue equals the foreign facility fee differential (\$15,000) multiplied by the number of FDF foreign facilities (216) plus the foreign facility fee differential (\$15,000) multiplied by the number of CMO foreign facilities (97), totaling \$4,695,000. This results in foreign fee differential revenue of \$4,695,000 from the total FDF and CMO facility fee target collection revenue. Subtracting the foreign facility differential fee revenue (\$4,695,000) from the total FDF and CMO facility target collection revenue (\$100,344,200) results in a remaining facility fee revenue balance of \$95,649,200. To determine the domestic FDF facility fee, FDA divides the \$95,649,200 by the total weighted number of FDF and CMO facilities (452.66), which results in a domestic FDF facility fee of \$211,305. The foreign FDF facility fee is \$15,000 more than the domestic FDF facility fee, or \$226,305.

According to GDUFA II, the domestic CMO fee is calculated as one-third the amount of the domestic FDF facility fee. Therefore, the domestic CMO fee is \$70,435, rounded to the nearest dollar. The foreign CMO fee is calculated as the domestic CMO fee plus the foreign fee differential of \$15,000. Therefore, the foreign CMO fee is \$85,435.

VII. API Facility Fee

Under GDUFA II, the annual API facility fee is owed by each person who owns a facility that is identified in (1) at least one approved generic drug submission or (2) in a Type II API DMF referenced in at least one approved generic drug submission. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(D) of the FD&C Act specifies the API facility fee will make up 7 percent of \$501,721,000 in fee revenue, which is \$35,120,470.

To calculate the API facility fee, data from FDA's IS were utilized as the primary source of facility information for determining the denominator. As stated above, IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as API manufacturers in at least one approved generic drug submission.

The total number of API facilities identified was 613; of that number, 79 were domestic and 534 were foreign facilities. The foreign facility differential is \$15,000. To calculate the fee for domestic facilities, FDA must first subtract the fee revenue that will result from the foreign facility fee differential. FDA takes the foreign facility differential (\$15,000) and multiplies it by the number of foreign facilities (534) to determine the total fee revenue that will result from the foreign facility differential. As a result of that calculation, the foreign fee differential revenue will make up \$8,010,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue (\$8,010,000) from the total API facility target revenue (\$35,120,470) results in a remaining balance of \$27,110,470. To determine the domestic API facility fee, we divide the \$27,110,470 by the total number of facilities (613), which gives us a domestic API facility fee of \$44,226. The foreign API facility fee is \$15,000 more than the domestic API facility fee, or \$59,226.

VIII. Generic Drug Applicant Program Fee

Under GDUFA II, if a person and its affiliates own at least one but not more than five approved ANDAs on October 1, 2018, the person and its affiliates shall owe a small business GDUFA program fee. If a person and its affiliates own at least 6 but not more than 19

approved ANDAs, the person and its affiliates shall owe a medium size operation GDUFA program fee. If a person and its affiliates own at least 20 approved ANDAs, the person and its affiliates shall owe a large size operation GDUFA program fee. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(E) of the FD&C Act specifies the GDUFA program fee will make up 35 percent of \$501,721,000 in fee revenue, which is \$175,602,350.

To determine the appropriate number of applicants for each tier, the Agency has posted lists of approved ANDAs on the FDA website (<https://www.fda.gov/gdufa>) and asked applicants on the list to claim which ANDAs and affiliates belong to the parent company. The original list of approved ANDAs came from the Agency's Document Archiving, Reporting, and Regulatory Tracking System (DARRTS), which included all ANDAs with the status of "approved" as of April 30, 2018.

In determining the appropriate number of approved ANDAs, the Agency has factored in a number of variables that could affect the collection of the target revenue: (1) Inactive ANDAs—applicants who have not submitted an annual report for one or

more of their approved applications within the past 2 years; (2) FY 2018 Program Fee Arrears List—applicants who failed to satisfy the FY 2018 program fee and were unresponsive to attempts to collect; and (3) Prediction of Approvals Due to Goal Dates and Office of Generic Drugs Approval Rate—Due to the low percentage of additional approved ANDAs for a specified time period and the difficulties in determining how this population would affect the program fee tier of each company, this variable was not included in the determination of the FY 2019 GDUFA program fee. The list of original approved ANDAs from the DARRTS database as of April 30, 2018, shows 259 applicants in the small business tier, 62 applicants in the medium size tier, and 58 applicants in the large size tier. This list also takes into account all the withdrawals, consolidations, and transfer of ownerships from industry as of April 30, 2018. Factoring in all the variables for the second year of GDUFA II, the Agency estimates there will be 177 applicants in the small business tier, 49 applicants in the medium size tier, and 57 applicants in the large size tier for FY 2019.

To calculate the GDUFA program fee, GDUFA II provides that large size

operation generic drug applicants pay the full fee, medium size operation applicants pay two-fifths of the full fee, and small business applicants pay one-tenth of the full fee. To generate the target collection revenue amount from GDUFA program fees (\$175,602,350), we must weigh medium and small tiered applicants as a subset of a large size operation generic drug applicant. FDA will set fees based on the weighted estimate of 17.70 applicants in the small business tier (177 multiplied by 10 percent), 19.60 applicants in the medium size tier (49 multiplied by 40 percent), and 57 applicants in the large size tier, arriving at 94.30 total weighted applicants for FY 2019.

To generate the large size operation GDUFA program fee, FDA divides the target revenue amount of \$175,602,350 by 94.30, which equals \$1,862,167. The medium size operation GDUFA program fee is 40 percent of the full fee (\$744,867), and the small business operation GDUFA program fee is 10 percent of the full fee (\$186,217).

IX. Fee Schedule for FY 2019

The fee rates for FY 2019 are set out in table 4.

TABLE 4—FEE SCHEDULE FOR FY 2019

Fee category	Fees rates for FY 2019
Applications:	
Abbreviated New Drug Application (ANDA)	\$178,799
Drug Master File (DMF)	55,013
Facilities:	
Active Pharmaceutical Ingredient (API) Domestic	44,226
API—Foreign	59,226
Finished Dosage Form (FDF)—Domestic	211,305
FDF—Foreign	226,305
Contract Manufacturing Organization (CMO)—Domestic	70,435
CMO—Foreign	85,435
GDUFA Program:	
Large size operation generic drug applicant	1,862,167
Medium size operation generic drug applicant	744,867
Small business operation generic drug applicant	186,217

X. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2018. To pay the ANDA, DMF, API facility, FDF facility, CMO facility, and GDUFA program fees, a Generic Drug User Fee Cover Sheet must be completed, available at <https://www.fda.gov/gdufa> and https://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp, and a user fee identification (ID) number must be generated. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S.

postal money order, credit card, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (Note: Only full payments are accepted; no partial payments can be made online.) Once an invoice is located, "Pay Now" should be selected to be redirected to <https://www.pay.gov/public/home> (Pay.gov).

Electronic payment options are based on the balance due. Payment by credit card is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA website after completing the Generic Drug User Fee

Cover Sheet and generating the user fee ID number.

The user fee ID number must be included on the check, bank draft, or postal money order and must be made payable to the order of the Food and Drug Administration. Payments can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197-9000. If checks are to be sent by a courier that requests a street address, the courier can deliver checks to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. For questions concerning courier delivery, U.S. Bank can be contacted at 314-418-4013. This telephone number is only for questions about courier delivery.) The FDA post office box number (P.O. Box 979108) must be written on the check, bank draft, or postal money order.

For payments made by wire transfer, the unique user fee ID number must be referenced. Without the unique user fee ID number, the payment may not be applied. If the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53-0196965.

Dated: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-16067 Filed 7-26-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2456]

Slowly Progressive, Low-Prevalence Rare Diseases With Substrate Deposition That Results From Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Slowly Progressive, Low-Prevalence Rare Diseases with Substrate Deposition That Results from Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies.” This document is intended to provide guidance to sponsors on the evidence necessary to demonstrate the effectiveness of new drugs, including biological drugs, or new drug uses intended for slowly progressive, low-prevalence rare diseases that are associated with substrate deposition and are caused by single enzyme defects. This guidance applies only to those low-prevalence rare diseases with a well-characterized pathophysiology and in which changes in substrate deposition can be readily measured in relevant tissue(s).

DATES: Submit either electronic or written comments on the draft guidance by September 25, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-D-2456 for “Slowly Progressive, Low-Prevalence Rare Diseases with Substrate Deposition That Results from Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies; Draft Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Dragos Roman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5152, Silver Spring, MD 20993-0002, 301-796-1285; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Slowly Progressive, Low-Prevalence Rare Diseases with Substrate Deposition That Results from Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies." This document is intended to provide guidance to sponsors on the evidence necessary to demonstrate the effectiveness of new

drugs or new drug uses intended for slowly progressive, low-prevalence rare diseases that are associated with substrate deposition and are caused by single enzyme defects. This guidance applies only to those low-prevalence rare diseases with a well-characterized pathophysiology and in which changes in substrate deposition can be readily measured in relevant tissue(s).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on providing evidence of effectiveness for replacement or corrective therapies intended for slowly progressive, low-prevalence rare diseases with substrate deposition that results from single enzyme defects. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 50 have been approved under OMB control number 0910-0755. The collections of information for expedited programs in the guidance for industry entitled "Expedited Programs for Serious Conditions—Drugs and Biologics" (available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm358301.pdf>) have been approved under OMB control number 0910-0765.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatory>

www.regulations.gov, or <https://www.regulations.gov>.

Dated: July 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-16036 Filed 7-26-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2493]

ICU Medical, Inc., et al.; Withdrawal of Approval of 31 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 31 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of August 27, 2018.

FOR FURTHER INFORMATION CONTACT:

Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945, Trang.Tran@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 020345	Aminosyn-HF (amino acids) Injection, 8%	ICU Medical, Inc., 600 North Field Dr., Lake Forest, IL 60045.
ANDA 040723	Isosorbide Dinitrate Extended-Release Tablets USP, 40 milligrams (mg).	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 064062	Amphotericin B for Injection USP, 50 mg/vial	Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618.
ANDA 064200	Cefotaxime for Injection USP, Equivalent to (EQ) 500 mg base/vial, EQ 1 gram (g) base/vial, and EQ 2 g base/vial.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.

Application No.	Drug	Applicant
ANDA 064201	Cefotaxime for Injection USP, EQ 10 g base/vial and EQ 20 g base/vial.	Do.
ANDA 065251	Cefuroxime for Injection USP, EQ 75 g base/bag and EQ 225 g base/bag (Pharmacy Bulk Package).	Samson Medical Technologies, LLC, 2050 Springdale Rd., P.O. Box 2730, Suite 400, Cherry Hill, NJ 08034.
ANDA 070892	Metoclopramide Hydrochloride (HCl) Injection, EQ 10 mg base/2 milliliters (mL).	Norbrook Laboratories, Ltd., c/o Norbrook, Inc., 9401 Indian Creek Pkwy., Suite 680, Overland Park, KS 66210.
ANDA 075309	Ticlopidine HCl Tablets USP, 250 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 076797	Risperidone Oral Solution USP, 1 mg/mL	Precision Dose, Inc., 722 Progressive Lane, South Beloit, IL 61080.
ANDA 077656	Thrive (nicotine polacrilex) Gum USP (Chewable), EQ 4 mg base.	GlaxoSmithKline Consumer Healthcare, 184 Liberty Corner Rd., Suite 200, Warren, NJ 07059.
ANDA 077658	Thrive (nicotine polacrilex) Gum USP (Chewable), EQ 2 mg base.	Do.
ANDA 080188	Testosterone Propionate Injection USP, 25 mg/mL, 50 mg/mL, and 100 mg/mL.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 083398	Prednisolone Acetate Injectable Suspension, 25 mg/mL	Do.
ANDA 083764	Prednisolone Acetate Injectable Suspension, 50 mg/mL	Do.
ANDA 084072	Triamcinolone Diacetate Injection, 40 mg/mL	Do.
ANDA 084270	Triamcinolone Tablets USP, 4 mg	Do.
ANDA 084466	Reserpine and Hydrochlorothiazide Tablets, 0.125 mg/25 mg	Do.
ANDA 084604	Procainamide HCl Capsules, 250 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 085693	Phentermine HCl Tablets USP, 8 mg	Sandoz, Inc., 4700 Sandoz Dr., Wilson, NC 27893.
ANDA 085863	Theophylline Elixir, 80 mg/15 mL	Precision Dose, Inc.
ANDA 087185	Ergoloid Mesylates Sublingual Tablets USP, 1 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087770	Sulfipyrazone Capsules USP, 200 mg	Do.
ANDA 088648	Methotrexate Injection USP, EQ 25 mg base/mL	Norbrook Laboratories, Ltd., c/o Norbrook, Inc.
ANDA 088928	Chlorzoxazone Tablets USP, 250 mg	Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 090663	Gemcitabine for Injection USP, EQ 200 mg base/vial and EQ 1 g base/vial.	Hameln RDS GmbH, c/o B&H Consulting Services, Inc., 50 Division St., Suite 206, Somerville, NJ 08876.
ANDA 091469	Vancomycin HCl for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).	Mylan Laboratories, Ltd., c/o Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 202390	Tramadol HCl Tablets USP, 50 mg	Accord Healthcare, Inc., 1009 Slater Rd., Suite 210-B, Durham, NC 27703.
ANDA 203506	Oxymorphone HCl Extended-Release Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 204320	Olanzapine Orally Disintegrating Tablets USP, 5 mg, 10 mg, 15 mg, and 20 mg.	Ajanta Pharma, Ltd., c/o Ajanta Pharma USA, Inc., 440 U.S. Highway 22 East, One Grande Commons, Suite 150, Bridgewater, NJ 08807.
ANDA 204706	Olopatadine HCl Ophthalmic Solution USP, EQ 0.1% base ...	Zambon S.p.A., c/o Camargo Pharmaceutical Services, LLC, 9825 Kenwood Rd., Suite 203, Cincinnati, OH 45242.
ANDA 207467	Nevirapine Extended-Release Tablets, 100 mg and 400 mg	Technology Organized, LLC, 9191 Point Replete Dr., Fort Belvoir, VA 22060.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 27, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on August 27, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: July 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-16037 Filed 7-26-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6380]

Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases.” FDA does not expect to grant any additional orphan-drug designation to drugs for pediatric subpopulations of common diseases (*i.e.*, diseases or conditions with an overall prevalence of 200,000 or greater). This will help resolve an unintended loophole in the Pediatric Research Equity Act (PREA) orphan exemption process where a sponsor holding a pediatric-subpopulation designation can submit a marketing application for use of its drug

in the non-orphan adult population of that disease, get a pediatric-subpopulation designation for the pediatric subset of the disease, and, due to this designation, be exempt from conducting the pediatric studies normally required under PREA when seeking approval of the adult indication.

DATES: The announcement of the guidance is published in the **Federal Register** on July 27, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-6380 for "Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations

of Common Diseases." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Office of Orphan Products Development, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5295, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for

electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Aaron Friedman, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5209, Silver Spring, MD 20993, 301-796-2989.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled "Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases." In the **Federal Register** of December 20, 2017 (82 FR 60402), FDA published a notice of availability for the draft guidance entitled "Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases," announcing that FDA does not expect to grant any additional orphan drug designation to drugs for pediatric subpopulations of common diseases (*i.e.*, diseases or conditions with an overall prevalence of over 200,000 in the United States). In the **Federal Register** of January 12, 2018 (83 FR 1619), FDA announced that it was extending the comment period for this draft guidance for an additional 30 days. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated December 2017. FDA does not expect to grant any additional orphan-drug designation to drugs for pediatric subpopulations of common diseases (*i.e.*, diseases or conditions with an overall prevalence of 200,000 or greater). This will help resolve an unintended loophole in the Pediatric Research Equity Act (PREA) orphan exemption process where a sponsor holding a pediatric-subpopulation designation can submit a marketing application for use of its drug in the non-orphan adult population of that disease, get a pediatric-subpopulation designation for the pediatric subset of the disease, and, due to this designation, be exempt from conducting the pediatric studies normally required under PREA when seeking approval of the adult indication.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on orphan designation of drugs and biologics for pediatric subpopulations of common diseases. It does not establish any rights for any person and is not binding on FDA or the

public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Orphan> or <https://www.regulations.gov>.

Dated: July 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-16027 Filed 7-26-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2478]

Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled “Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Draft Guidance for Industry.” The draft guidance document notifies blood establishments that collect blood and blood components that we have determined babesiosis to be a relevant transfusion-transmitted infection (RTTI) and provides recommendations for donor screening, donation testing, donor deferral, and product management to reduce the risk of transfusion-transmitted babesiosis (TTB). The recommendations contained in the guidance apply to the collection of blood and blood components, except Source Plasma.

DATES: Submit either electronic or written comments on the draft guidance by September 25, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-D-2478 for “Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Draft Guidance for Industry.” The draft guidance document

notifies blood establishments that collect blood and blood components that we have determined babesiosis to be an RTTI under 21 CFR 630.3(h)(2) and provides recommendations for donor screening, donation testing, donor deferral, and product management to reduce the risk of TTB. The recommendations contained in the draft guidance document applies to the collection of blood and blood components, except Source Plasma.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on recommendations for reducing the risk of transfusion-transmitted babesiosis. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338, and the collections of information in 21 CFR part 606, 21 CFR 610.40(h), and 21 CFR 630.40 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: July 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16030 Filed 7–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2494]

Peripheral Vascular Atherectomy Devices—Premarket Notification Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions.” This draft guidance provides recommendations for premarket submissions for a new or modified peripheral vascular atherectomy device. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by September 25, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2018–D–2494 for “Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov>.

www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Misti Malone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 120, Silver Spring, MD 20993–0002, 301–796–2520.

SUPPLEMENTARY INFORMATION:

I. Background

Atherectomy is an interventional procedure performed to debulk atherosclerotic plaque from diseased arteries. Atherectomy has been used in treatment of both coronary and peripheral arterial disease. FDA has developed this draft guidance for members of industry who submit and FDA staff who review premarket submissions for atherectomy devices used in the peripheral vasculature. When finalized, this guidance is intended to provide recommendations for information to include in premarket notifications (510(k)) for peripheral vascular atherectomy devices (e.g., descriptive characteristics, labeling, biocompatibility, sterility, non-clinical, animal, and clinical performance testing).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16013 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB Control No.
807, subpart E	Premarket Notification	0910–0120
812	Investigational Device Exemption	0910–0078
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073
807, subparts A through D	Electronic Submission of Medical Device Registration and Listing	0910–0625
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910–0755
56	Institutional Review Boards	0910–0130
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies	0910–0119
801.150(a)(2) and (e)	Agreement for Shipments of Devices for Sterilization	0910–0131

Dated: July 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16029 Filed 7–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2775]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

fiscal year (FY) 2019 fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections that are authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). These fees are effective on October 1, 2018, and will remain in effect through September 30, 2019.

FOR FURTHER INFORMATION CONTACT:

Jason Lewis, Office of Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rm. 2406, Rockville, MD 20857,

301-796-5957, email: Jason.Lewis@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 107 of FSMA (Pub. L. 111-353) added section 743 to the FD&C Act (21 U.S.C. 379j-31) to provide FDA with the authority to assess and collect fees from, in part: (1) The responsible party for each domestic facility and the U.S. agent for each foreign facility subject to a reinspection, to cover reinspection-related costs; (2) the responsible party for a domestic facility and an importer who does not comply with a recall order, to cover food¹ recall activities associated with such order; and (3) each importer subject to a reinspection to cover reinspection-related costs (section 743(a)(1)(A), (B), and (D) of the FD&C Act). Section 743 of the FD&C Act directs FDA to establish fees for each of these activities based on an estimate of 100 percent of the costs of each activity for each year (section 743(b)(2)(A)(i), (ii), and (iv)), and these fees must be made available solely to pay for the costs of each activity for which the fee was incurred (section 743(b)(3)). These fees are effective on October 1, 2018, and will remain in effect through September 30, 2019. Section 743(b)(2)(B)(iii) of the FD&C Act directs FDA to develop a proposed set of guidelines in consideration of the burden of fee amounts on small businesses. As a first step in developing these guidelines, FDA invited public comment on the potential impact of the fees authorized by section 743 of the FD&C Act on small businesses (76 FR 45818, August 1, 2011). The comment period for this request ended November 30, 2011. As stated in FDA's September 2011 "Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act," (<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments/RegulatoryInformation/FoodDefense/ucm274176.htm>), because FDA recognizes that for small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, FDA intends to consider reducing certain fees for those firms. FDA does not intend to issue invoices for reinspection or recall order fees until FDA publishes a guidance document outlining the process through

which firms may request a reduction in fees.

In addition, as stated in the September 2011 Guidance, FDA is in the process of considering various issues associated with the assessment and collection of importer reinspection fees. The fee rates set forth in this notice will be used to determine any importer reinspection fees assessed in FY 2019.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2019

FDA is required to estimate 100 percent of its costs for each activity to establish fee rates for FY 2019. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology (IT), and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2019

Full-time equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered "hours worked" for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: Payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2019 cost. The FY 2019 FDA-wide average cost for payroll (salaries and benefits) is \$157,731; non-payroll—including equipment, supplies, IT, general and administrative overhead—is \$91,008; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is \$24,400 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2019 average fully supported cost to \$273,139 per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2019 prior to including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2019 average fully supported cost of \$273,139 per FTE by the average number of supported direct FDA work hours in FY 2017—the last FY for which data are available. See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2017

Total number of hours in a paid staff year	2,080
Less:	
10 paid holidays	– 80
20 days of annual leave	– 160
10 days of sick leave	– 80
12.5 days of training	– 100
26.5 days of general administration	– 184
26.5 days of travel	– 212
2 hours of meetings per week	– 104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2019 (\$273,139) by the total number of supported direct work hours available for assignment in FY 2017 (1,160) results in an average fully supported cost of \$235 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2019.

B. Adjusting FY 2017 Travel Costs for Inflation To Estimate FY 2019 Travel Costs

To adjust the hourly rate for FY 2019, FDA must estimate the cost of inflation in each year for FY 2018 and FY 2019. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2018 inflation rate to be 1.6868 percent; this rate was published in the FY 2018 PDUFA user fee rates notice in the **Federal Register** (September 14, 2017, 82 FR 43244). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.6868 percent for 2018 and 1.7708 percent for 2019, and FDA intends to use these inflation rates to make inflation adjustments for FY 2019 for several of its user fee programs; the derivation of this rate will be published in the **Federal Register** in the FY 2019 notice for the PDUFA user fee rates.

The average fully supported cost per supported direct FDA work hour, excluding travel costs of \$235 already takes into account inflation as the calculation above is based on FY 2019

¹ The term "food" for purposes of this document has the same meaning as such term in section 201(f) of the FD&C Act (21 U.S.C. 321(f)).

predicted costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2019 prior to including domestic or foreign travel costs as applicable for the activity. In FY 2017, FDA's Office of Regulatory Affairs (ORA) spent a total of \$5,846,091 for domestic regulatory inspection travel costs and General Services

Administration Vehicle costs related to FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) field activities programs. The total ORA domestic travel costs spent is then divided by the 10,289 CFSAN and CVM domestic inspections, which averages a total of \$568 per inspection. These inspections average 34.05 hours per inspection. Dividing \$568 per inspection by 34.05 hours per inspection results in a total and an additional cost of \$17 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2017. To adjust for the \$17 per hour additional domestic cost inflation increases for FY 2018 and FY 2019, FDA must multiply the FY 2018 PDUFA inflation rate adjustor (1.016868) times the FY 2019 PDUFA inflation rate adjustor (1.017708) times the \$17 additional domestic cost, which results in an estimated cost of \$18 (rounded to the nearest dollar) per paid hour in addition to \$235 for a total of \$253 per paid hour (\$235 plus \$18) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2019 when domestic travel is required.

In FY 2017, ORA spent a total of \$2,566,050 on 480 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of \$5,346 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing \$5,346 per trip by 120 hours per trip results in a total and an additional cost of \$45 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2017. To adjust \$45 for inflationary increases in FY 2018 and FY 2019, FDA must multiply it by the same inflation factors mentioned previously in this document (1.016868 and 1.017708), which results in an estimated cost of \$47 (rounded to the nearest dollar) per paid hour in addition to \$235 for a total of \$282 per paid hour (\$235 plus \$47) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2019 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2019

Fee category	Fee rates for FY 2019
Hourly rate if domestic travel is required	\$253
Hourly rate if foreign travel is required	282

III. Fees for Reinspections of Domestic or Foreign Facilities Under Section 743(a)(1)(A)

A. What will cause this fee to be assessed?

The fee will be assessed for a reinspection conducted under section 704 of the FD&C Act (21 U.S.C. 374) to determine whether corrective actions have been implemented and are effective and compliance has been achieved to the Secretary of Health and Human Services' (the Secretary) (and, by delegation, FDA's) satisfaction at a facility that manufactures, processes, packs, or holds food for consumption necessitated as a result of a previous inspection (also conducted under section 704) of this facility, which had a final classification of Official Action Indicated (OAI) conducted by or on behalf of FDA, when FDA determined the non-compliance was materially related to food safety requirements of the FD&C Act. FDA considers such non-compliance to include non-compliance with a statutory or regulatory requirement under section 402 of the FD&C Act (21 U.S.C. 342) and section 403(w) of the FD&C Act (21 U.S.C. 343(w)). However, FDA does not consider non-compliance that is materially related to a food safety requirement to include circumstances where the non-compliance is of a technical nature and not food safety related (e.g., failure to comply with a food standard or incorrect font size on a food label). Determining when non-compliance, other than under sections 402 and 403(w) of the FD&C Act, is materially related to a food safety requirement of the FD&C Act may depend on the facts of a particular situation. FDA intends to issue guidance to provide additional information about the circumstances under which FDA would consider non-compliance to be materially related to a food safety requirement of the FD&C Act.

Under section 743(a)(1)(A) of the FD&C Act, FDA is directed to assess and collect fees from "the responsible party for each domestic facility (as defined in section 415(b) (21 U.S.C. 350d(b))) and the United States agent for each foreign

facility subject to a reinspection" to cover reinspection-related costs.

Section 743(a)(2)(A)(i) of the FD&C Act defines the term "reinspection" with respect to domestic facilities as "1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified non-compliance materially related to a food safety requirement of th[e] Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction."

The FD&C Act does not contain a definition of "reinspection" specific to foreign facilities. In order to give meaning to the language in section 743(a)(1)(A) of the FD&C Act to collect fees from the U.S. agent of a foreign facility subject to a reinspection, the Agency is using the following definition of "reinspection" for purposes of assessing and collecting fees under section 743(a)(1)(A), with respect to a foreign facility, "1 or more inspections conducted by officers or employees duly designated by the Secretary subsequent to such an inspection which identified non-compliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction."

This definition allows FDA to fulfill the mandate to assess and collect fees from the U.S. agent of a foreign facility in the event that an inspection reveals non-compliance materially related to a food safety requirement of the FD&C Act, causing one or more subsequent inspections to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction. By requiring the initial inspection to be conducted by officers or employees duly designated by the Secretary, the definition ensures that a foreign facility would be subject to fees only in the event that FDA, or an entity designated to act on its behalf, has made the requisite identification at an initial inspection of non-compliance materially related to a food safety requirement of the FD&C Act. The definition of "reinspection-related costs" in section 743(a)(2)(B) of the FD&C Act relates to both a domestic facility reinspection and a foreign facility reinspection, as described in section 743(a)(1)(A).

B. Who will be responsible for paying this fee?

The FD&C Act states that this fee is to be paid by the responsible party for each domestic facility (as defined in section 415(b) of the FD&C Act) and by the U.S. agent for each foreign facility (section 743(a)(1)(A) of the FD&C Act). This is

the party to whom FDA will send the invoice for any fees that are assessed under this section.

C. How much will this fee be?

The fee is based on the number of direct hours spent on such reinspections, including time spent conducting the physical surveillance and/or compliance reinspection at the facility, or whatever components of such an inspection are deemed necessary, making preparations and arrangements for the reinspection, traveling to and from the facility, preparing any reports, analyzing any samples or examining any labels if required, and performing other activities as part of the OAI reinspection until the facility is again determined to be in compliance. The direct hours spent on each such reinspection will be billed at the appropriate hourly rate shown in table 2 of this document.

IV. Fees for Non-Compliance With a Recall Order Under Section 743(a)(1)(B)

A. What will cause this fee to be assessed?

The fee will be assessed for not complying with a recall order under section 423(d) (21 U.S.C. 350l(d)) or section 412(f) of the FD&C Act (21 U.S.C. 350a(f)) to cover food recall activities associated with such order performed by the Secretary (and by delegation, FDA) (section 743(a)(1)(B) of the FD&C Act). Non-compliance may include the following: (1) Not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

B. Who will be responsible for paying this fee?

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

C. How much will this fee be?

The fee is based on the number of direct hours spent on taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and

from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

V. How must the fees be paid?

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 90 days of the invoice date in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

VI. What are the consequences of not paying these fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-16069 Filed 7-26-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the President's Council on Sports, Fitness, and Nutrition

AGENCY: President's Council on Sports, Fitness, and Nutrition, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the President's Council on Sports, Fitness, and Nutrition (PCSFN) will hold its annual meeting. The meeting will be open to the public.

DATES: The meeting will be held on September 21, 2018, from 9:30 a.m. to 12:30 p.m.

ADDRESSES: Newseum, Knight Conference Center 7th Floor, 555 Pennsylvania Ave. NW, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Ms. Holli M. Richmond, Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, Tower Building, 1101 Wootton Parkway, Suite 560, Rockville, MD 20852, (240) 276-

9567. Information about PCSFN, including details about the upcoming meeting, can be obtained at www.fitness.gov.

SUPPLEMENTARY INFORMATION: The primary functions of the PCSFN include (1) advising the President, through the Secretary, concerning progress made in carrying out the provisions of Executive Order 13265, as amended by Executive Order 13824, and recommending to the President, through the Secretary, actions to accelerate such progress; (2) recommending to the Secretary a national strategy to expand children's participation in youth sports, encourage regular physical activity, including active play and promote good nutrition for all Americans. Recommendations may address, but are not necessarily limited to, increasing awareness of the benefits of participation in sports and regular physical activity, as well as the importance of good nutrition; promoting private and public sector strategies to increase participation in sports, encourage regular physical activity, and improve nutrition; developing metrics that gauge youth sports participation and physical activity to inform efforts that will improve participation in sports and regular physical activity among young Americans; and establishing a national and local strategy to recruit volunteers who will encourage and support youth participation in sports and regular physical activity, through coaching, mentoring, teaching, or administering athletic and nutritional programs. The Council's performance of these functions shall take into account the Department of Health and Human Services' Physical Activity Guidelines for Americans, including consideration for youth with disabilities.

The Council shall meet, at a minimum, one time per fiscal year. The meeting will be held to (1) assess ongoing Council activities; and, (2) discuss and plan future projects and programs. The agenda for the planned meeting is being developed and will be posted at www.fitness.gov when it has been finalized.

The meeting that is scheduled to be held on September 21, 2018, is open to the public and the media. Every effort will be made to provide reasonable accommodations for persons with disabilities and/or special needs who wish to attend the meeting. Persons with disabilities and/or special needs should call (240) 276-9567 no later than close of business Monday, September 10, 2018, to request accommodations. Members of the public who wish to attend the meeting are asked to pre-register by sending an email to

rsvp.fitness@hhs.gov or by calling (240) 276-9567. Registration for public attendance must be completed before close of business Wednesday, September 12, 2018.

Dated: July 12, 2018.

Holli M. Richmond,

Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, U.S. Department of Health and Human Services.

[FR Doc. 2018-16056 Filed 7-26-18; 8:45 am]

BILLING CODE 4150-35-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Molecular Targeting Technologies, Inc. (MTTI); a Delaware corporation, with its principle place of business in West Chester, Pennsylvania, to practice the inventions embodied in the patent application listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development August 27, 2018 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone number 301-435-5019, or shmilovm@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to MTTI: HHS Ref. E-150-2016-1-PCT-01, International Patent Application PCT/US2017/054863 filed October 3, 2017, entitled "Chemical Conjugates of Evans Blue Derivatives and Their Use As Radiotherapy And Imaging Agents."

The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective patent license will be granted worldwide and in a field of use not broader than radiotherapeutics for somatostatin-receptor expressing neuroendocrine tumors.

The invention pertains to a radiotherapeutic against neuroendocrine tumors that express somatostatin receptor. Radionuclide therapies directed against tumors that express somatostatin receptors (SSTRs) have proven effective for the treatment of advanced, low- to intermediate-grade neuroendocrine tumors. The subject radiotherapeutic covered by the subject patent estate includes a somatostatin (SST) peptide derivative like octreotate (TATE), conjugated to an Evans Blue (EB) analog, and further chelated via DOTA to therapeutic radionuclide ¹⁷⁷Lu, a beta emitter. The EB analog reversibly binds to circulating serum albumin and improves the pharmacokinetics of SST peptide derivatives and reduce peptide-receptor radionuclide therapy toxicity. EB analog conjugated to octreotate (EB-DOTATATE) has been shown by the inventors to provide reversible albumin binding *in vivo* and extended half-life in circulation. When EB-TATE is slowly released into the tumor microenvironment, tumor uptake and internalization into SSTR positive tumors resulted in delivery of radioactive particles and tumor cell killing. EB-TATE displayed significantly more favorable pharmacokinetics than TATE alone by achieving higher tumor to non-tumor penetration as evidenced by positron emission tomography.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: July 20, 2018.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2018-16065 Filed 7-26-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; U01 SEP: Glycobiologists Alliance for Cancer Research.

Date: August 30, 2018.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W102, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Shakeel Ahmad, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Bethesda, MD 20892-9750, 240-276-6349, ahmads@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project IV (P01).

Date: September 27-28, 2018.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Sanita Bharti, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W122, Bethesda, MD 20892-9750, 240-276-5909, sanitab@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention

Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 23, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-16008 Filed 7-26-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice To Announce Commission of a Surgeon General's Report on Oral Health

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: On behalf of the United States Department of Health and Human Services, the Office of the Surgeon General, the National Institutes of Health, and the National Institute of Dental and Craniofacial Research, the U.S. Public Health Service's Oral Health Coordinating Committee announces the commission of a Surgeon General's Report presenting prominent issues affecting oral health. The report will document progress in oral health in the twenty years since the 2000 Surgeon General's Report on Oral Health, identify existing knowledge gaps, and articulate a vision for the future.

FOR FURTHER INFORMATION CONTACT:

Bruce A. Dye, DDS, MPH, Dental Epidemiology Officer, Office of Science Policy and Analysis, NIDCR, NIH, 31 Center Drive, Room 5B55, Rockville, MD, 20892. Phone: 301-496-7765, Email: bruce.dye@nih.gov.

SUPPLEMENTARY INFORMATION:

Scope of Problem: The charge for the first Surgeon General's report on oral health in 2000 was to define, describe, and evaluate the interaction between oral health and health and well-being (quality of life), through the lifespan in the context of changes in society. The overarching message from that report clearly communicated that oral health is essential to the general health and well-being of all Americans and can be achieved by all. In the intervening two decades, oral health has improved for many Americans, but not for all. Many Americans are retaining more of their natural teeth, complete tooth loss among older adults is at the lowest level ever

measured, and many younger children have less untreated tooth decay. Over the past two decades, we have learned more about how changes across the lifespan can substantially influence oral health and how health promotion activities and interventions targeted for specific life stages can benefit oral health and quality of life. However, many Americans continue to experience unnecessary pain and complications from poor oral health that adversely affect their well-being, adding substantial economic and social costs. Poor oral health also impacts our nation's ability to recruit young adults for military service and maintain military readiness.

Oral health workforce models and care delivery systems have evolved in the past two decades. There has been a substantial effort to incorporate early detection and preventive oral health measures into primary care settings and the expansion of the State Children's Health Insurance Program, Medicaid, and other health insurance programs have helped many Americans of all ages. Yet, as there have been some successes in integrating oral health into the broader health care system in the United States, many still view oral health care as a supplemental benefit, and not a priority benefit. This separate view of oral health negatively impacts our nation in a variety of ways, including the increasing use of emergency departments at substantial cost to treat dental pain and related conditions. Finally, the increasing problems of substance misuse and use disorders during the past two decades have impacted oral health at the patient, community, and provider level, which has raised awareness of the need to address dental provider prescribing patterns and pain management practices.

The first Surgeon General's report on oral health addressed determinants for oral health and disease. Twenty years later, the knowledge gained from science and technology has continued to provide a better understanding of the etiology and natural history of oral and craniofacial diseases and conditions, and we have gained a better understanding of these determinants. This knowledge has led to therapeutic interventions that have improved oral health over the past two decades. Ongoing research is improving our understanding of the biological influences on oral health, the relationship between oral diseases and general health, the role of technology and advanced materials in improving dental care, and the benefits of good oral health to overall well-being and the

community. Although we benefit from numerous advances that influence oral health, we still face challenges as we try to reach our goal of oral health for all.

Approach: The scope of the Surgeon General's Report is intended to be broad and comprehensive, with the goal of mapping the current landscape of the key issues that affect oral health. It will present information from a variety of data sources such as the National Health and Nutrition Examination Survey, Medical Expenditure Panel Survey, Behavioral Risk Factor Surveillance System, and others. These sources highlight changes in oral health over time, providing opportunities to monitor how determinants for health have changed, and the effect of those changes over the past 20 years. The report is intended to: (1) Underscore the critical nature of poor oral health as a public health issue; (2) provide a comprehensive review of the importance of oral health throughout life; (3) describe important contemporary issues affecting oral health and the promise of science to transform the oral health of the nation; (4) outline a vision for future directions; and (5) educate, encourage, and call upon all Americans to take action.

Potential Areas of Focus: Areas of focus in the report may include a description of the epidemiology of diseases and conditions that affect the craniofacial complex; a review of health promotion and disease prevention activities; factors that affect the etiology of poor oral health at the individual and population level; social determinants of health and their influence on oral health disparities; biological factors including the microbiome; social, economic, and health consequences of poor oral health; mental health, substance misuse and addiction impact on the oral health of individuals, providers, and communities; the state of oral health care access and coverage as it relates to prevention and treatment for dental diseases and related conditions; integration of oral health into primary health care settings; organization and financing of the provision of dental care within the health care system; ethical, legal, and policy issues; and the application of scientific research in the field, including methods, challenges, and current and future directions.

Dated: July 21, 2018.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2018-16096 Filed 7-26-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cancer Immunotherapy

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. Patents and Patent Applications listed in the Supplementary Information section of this notice to Midissia Therapeutics ("Midissia") located in San Francisco, CA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before August 13, 2018 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Ricquita Pollard, Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702; Telephone: (240) 276-5530; Facsimile: (240) 276-5504; Email: pollardrd@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 62/248,964 filed Oct. 30, 2015 for "Compositions and Methods for the Treatment of HER2-Expressing Solid Tumor" [HHS Ref. No. E-187-2015/0US-01];
2. International Patent Application No. PCT/US2016/059680 filed October 31, 2016 for "Compositions and Methods for Treatment of HER2-Expressing Solid Tumor" [HHS Reference No. E-187-2015/0-PCT-02];
3. Canadian National Stage Patent Application (*No. not yet assigned*), filed April 30, 2018 [HHS Ref. No. E-187-2015/0-CA-03];
4. Japanese National Stage Patent Application No. 2018-521518, filed April 30, 2018 [HHS Ref. No. E-187-2015/0-JP-04];
5. Australian National Stage Patent Application No. 2016343845, filed April 30, 2018 [HHS Ref. No. E-187-2015/0-AU-05];

6. European National Stage Patent Application. (*No. not yet assigned*), filed April 30, 2018 [HHS Ref. No. E-187-2015/0-EP-06];
7. U.S. National Stage Patent Application No. 15/771,932, filed April 30, 2018 [HHS Ref. No. E-187-2015/0-US-07];

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to "development and commercialization of Ad-HER2 vaccines as a therapeutic against HER2-positive cancers as covered within the scope of the Licensed Patent Rights, excluding uses in combination with vectors/adjuvants, checkpoint inhibitors or other immune modulators."

This technology describes a recombinant adenoviral vector that expresses the extracellular (EC) and transmembrane (TM) domains of the human HER2 protein and is designed to induce a polyclonal anti-tumor response. HER2 is a member of the epidermal growth factor family and is overexpressed in subsets of breast, ovarian, gastric, colorectal, pancreatic and endometrial cancers. This vaccine encodes for the entire EC and TM domains of human HER2neu and is specifically contained within a recombinant adenoviral vector that has the knob of Adenovirus 5 and substituted fiber of Adenovirus 35. The substitution of the knob of Adenovirus 35 whose receptor is CD46 allows for efficient and maximal transduction of human dendritic and hematopoietic cells.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as

required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 19, 2018.

Richard U. Rodriguez,
Associate Director, Technology Transfer
Center, National Cancer Institute.

[FR Doc. 2018-16058 Filed 7-26-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Intramural Continuing Umbrella of Research Experiences (iCURE) Application (National Cancer Institute)

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Alison Lin, 9609 Medical Center Drive, Rockville, MD 20850 or call non-toll-free number (240) 276-6177 or Email your request, including your address to: linaj@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the

proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Intramural Continuing Umbrella of Research Experiences (iCURE) Application, 0925-XXXX, Exp., Date XX/XXXX, EXISTING COLLECTION IN USE WITHOUT OMB APPROVAL, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The new Intramural Continuing Umbrella of Research Experiences (iCURE) program supports mentored research experiences for qualified post-baccalaureate (including post masters) individuals, graduate students, and postdoctoral fellows in the multidisciplinary National Cancer Institute (NCI) intramural research environment. This information collection request are applications and a reference letter to help evaluate the merits of the candidates and their potential match for the iCURE program. iCURE is an extension of the highly successful NCI Center to Reduce Cancer Health Disparities' (CRCHD) Continuing Umbrella of Research Experiences (CURE) program which helps support the career progress of its scholars

toward research independence, as well as fosters and sustains diversity in the biomedical research pipeline. Like the CURE program, iCURE strongly encourages the participation of individuals from underrepresented populations and is aligned with NCI's interest in diversity. The benefit of collecting this information is to enable the selection of the best matching candidates for the iCURE program. The iCURE program aims to, 1. Enhance the diversity of the NCI Intramural Research Program (IRP), and 2. Promote the career progress of the iCURE scholars in cancer research.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated burden hours are 305.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Postbac Supplemental Application ...	Post-Baccalaureate (Including Post-Master's) Individuals.	50	1	30/60	25
Graduate Student Application	Graduate Students	30	1	2	60
Postdoctoral Fellowship Application	Postdoctoral Candidates	50	1	2	100
Reference Letter	PIs, professors, supervisors	240	1	30/60	120
Total	370	370	305

Patricia M. Busche,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2018-16053 Filed 7-26-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke, Muscular Dystrophy Coordinating Committee Call for Committee Membership Nominations

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Office of the Secretary of the Department of Health and Human Services (HHS) is seeking nominations for an individual to serve as a nonfederal public member on the Muscular Dystrophy Coordinating Committee.

DATES: Nominations are due by 5 p.m. EDT on August 31, 2018.

ADDRESSES: Nominations must be sent to Glen Nuckolls, Ph.D., by email to nuckollg@ninds.nih.gov.

FOR FURTHER INFORMATION CONTACT: Glen Nuckolls, Ph.D., by email to nuckollg@ninds.nih.gov or (301) 496-5745.

SUPPLEMENTARY INFORMATION: The Muscular Dystrophy Coordinating Committee (MDCC) is a federal advisory committee established in accordance with the Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2001 (MD-CARE Act; Pub. L. 107-84). The MD-CARE Act was reauthorized in 2008 by Public Law 110-361, and again in 2014 by Public Law 113-166. The MD-CARE Act specifies that the committee membership be composed of $\frac{2}{3}$ governmental agency representatives and $\frac{1}{3}$ public members. We are seeking nominations for two non-federal, public members at this time, due to turnover of committee membership. Nominations will be accepted between July 31 and August 31, 2018.

Who is Eligible: Nominations are encouraged for new or reappointment of non-federal public members who can provide the public and/or patient perspectives to discussions of issues considered by the Committee. Self-

nominations and nominations of other individuals are both permitted. Only one nomination per individual is required. Multiple nominations for the same individual will not increase likelihood of selection. Non-federal, public members may be selected from the pool of submitted nominations or other sources as needed to meet statutory requirements and to form a balanced committee that represents the diversity within the muscular dystrophy communities. Nominations are especially encouraged from leaders or representatives of muscular dystrophy research, advocacy, or service organizations, individuals with muscular dystrophy or their parents or guardians. In accordance with White House Office of Management and Budget guidelines (FR Doc. 2014-19140), federally-registered lobbyists are not eligible.

Committee Composition: The Department strives to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that the views of all genders, all ethnic and racial groups, and people with disabilities are

represented on HHS Federal advisory committees and, therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Committee. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status. Requests for reasonable accommodation to enable participation on the Committee should be indicated in the nomination submission.

Member Terms: Non-Federal public members of the Committee serve for a term of 3 years, and may serve for an unlimited number of terms if reappointed. Members may serve after the expiration of their terms, until their successors have taken office.

Meetings and Travel: As specified by Public Law 113–166, the MDCC “shall meet no fewer than two times per calendar year.” Travel expenses are provided for non-federal public Committee members to facilitate attendance at in-person meetings. Members are expected to make every effort to attend all full committee meetings, twice per year, either in person or via remote access. Participation in relevant subcommittee, working and planning group meetings, and workshops, is also encouraged.

Submission Instructions and Deadline: Nominations are due by 5 p.m. EDT on August 31, 2018, and should be sent to Glen Nuckolls, Ph.D., by email to nuckollg@ninds.nih.gov.

Nominations must include contact information for the nominee, a current curriculum vitae or resume of the nominee and a paragraph describing the qualifications of the person to represent some portion(s) of the muscular dystrophy research, advocacy and/or patient care communities.

More information about the MDCC is available at <https://mdcc.nih.gov/>.

Dated: July 24, 2018.

Walter J. Koroshetz,

Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health.

[FR Doc. 2018–16112 Filed 7–26–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Radiotherapy for Metastatic Castration-Resistant Prostate Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive commercialization patent license to Sinotau Pharmaceutical Group, headquartered in Beijing, China, to practice the inventions embodied in the patent application(s) listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development August 27, 2018 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479, phone number 301–435–5019, or shmilovm@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to Sinotau Pharmaceutical Group: U.S. Provisional Patent Application 62/633,648, “Chemical Conjugates Of Evans Blue Derivatives And Their Use As Radiotherapy And Imaging Agents For Targeting Prostate Cancer,” filed February 22, 2018 (HHS Ref. No. E–054–2018–0). The patent rights in this invention have been assigned to the Government of the United States of America. The perspective license would be granted worldwide and in a field of use not broader than radiotherapeutics for metastatic castration-resistant prostate cancer.

The invention covered by the patents and patent applications pertaining to HHS Ref. No. E–054–2018–0 pertain to a therapeutic agent that includes a

chemically conjugated residue derived from (((R)-1-carboxy-2-mercaptoethyl)carbamoyl)-L-glutamic acid that is further bound to an Evans blue analog (EB). The EB analog reversibly binds to circulating serum albumin to provide a radiopharmaceutical that retains affinity and specificity to prostate specific membrane antigen (PSMA; in this case PSMA-617). PSMA is a surface molecule shown to be specifically expressed by prostate tumor cells. PSMA expression levels correlate with disease stage and with hormone refractory cancers. Although most PSMA expression appears to be restricted to the prostate cancer, low levels of expression can also be detected in the brain, kidneys, salivary glands, and small intestine. The antigen is also shown to be expressed by neovascular tumor vessels of multiple other cancers. Inclusion of the Evans blue analog promotes high internalization and retention rates of the conjugated target ligand, and therefore, higher accumulation in PSMA positive tumors. Labeling EB-PSMA-617 derivatives with the therapeutic beta emitters, e.g., ⁹⁰Y, ⁸⁶Y, and ¹⁷⁷Lu gives rise to improved tumor response and survival rates.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: July 19, 2018.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2018–16066 Filed 7–26–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice to Close Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; NIAMS Peer Review Meeting.

Date: August 8, 2018.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Health/NIAMS, 6701 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Kathy Salaita, SCD, Chief, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Blvd., Room 3172, Bethesda, MD 20892, (301) 806-8250, salaitak@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis and Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: July 23, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-16060 Filed 7-26-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Network Trials—Panel 1.

Date: August 3, 2018.

Time: 12:30 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, (301) 435-6033, rajarams@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Network Trials—Panel 2.

Date: August 14, 2018.

Time: 10:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, (301) 435-6033, rajarams@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: July 23, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-16061 Filed 7-26-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Collection of Customer Service, Demographic, and Smoking/Tobacco Use Information From the National Cancer Institute's Contact Center (CC) Clients (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received August 27, 2018.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Mary Anne Bright, Supervisory Public Health Advisor, CCPIB/OCPL, 9609 Medical Center Drive, Rockville, MD 20850, or call non-toll-free number 240-276-6647 or Email your request, including your address to: brightma@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on May 14, 2018, page 22275 (83 FR 22275) and allowed 60 days for public comment. No public comments were received. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and

approval of the information collection listed below.

Proposed Collection: Collection of Customer Service, Demographic, and Smoking/Tobacco use Information from the National Cancer Institute's Contact Center (CC) Clients, 0925-0208 Expiration Date 04/30/2019, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) currently collects: (1) Customer service and demographic

information from clients of the Contact Center (CC) in order to properly plan, implement, and evaluate cancer education efforts, including assessing the extent by which the CC reaches and impacts underserved populations; (2) smoking/tobacco use behavior of individuals seeking NCI's smoking cessation assistance through the CC in order to provide smoking cessation services tailored to the individual client's needs and track their smoking behavior at follow up. This is a request for OMB to approve a revised

submission for an additional three years to provide ongoing customer service collection of demographic information, and collection of brief customer satisfaction questions from NCI Contact Center Clients for the purpose of program planning and evaluation.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,875.

Estimated Annualized Burden Hours

TABLE A. 12-1—ESTIMATE OF ANNUAL BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Frequency of responses	Average time per response (minutes/hour)	Annual burden hours
Telephone Clients (Appendix 1A)	Customer Service	31,562	1	1/60	526
	Demographic & Customer Satisfaction Questions.	13,100	1	2/60	437
Smoking Cessation Clients	Smoking Cessation "Intake" Questions (Appendix 1C).	3,380	1	6/60	338
	Customer Satisfaction Questions (Appendix 9).	676	1	2/60	23
VA Smoking Cessation Clients	Call Backs (Appendix 1D)	1,560	1	4/60	104
VA Follow Up Calls	Call Backs (Appendix 1E)	936	1	4/60	62
LiveHelp Clients	Demographic & Customer Satisfaction Questions (Appendix 1B).	6,236	1	2/60	208
Email Clients	Email Intake Form (Appendix 2)	1,002	1	10/60	167
Total	58,452	58,452	1,875

Dated: July 16, 2018.

Karla C. Bailey,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2018-16048 Filed 7-26-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information

are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Testing of Electronic Health Records Questions for the National Survey of Substance Abuse Treatment Services (N-SSATS) and the National Mental Health Services Survey (N-MHSS)—NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Health Statistics and Quality (CBHSQ), is requesting approval for conducting cognitive testing on the use of electronic health records (EHRs) by substance abuse and mental health treatment facilities in the United States. The final goal of this cognitive testing is to incorporate questions on electronic health records to SAMHSA's National

Survey of Substance Abuse Treatment Services (N-SSATS) and the National Mental Health Services Survey (N-MHSS).

Currently, there is a lack of national level data that exists on behavioral health care providers' progress toward interoperability. The National Council for Behavioral Health in 2011/2012 conducted a survey to determine health information technology (IT) readiness. This data focused only on the membership of the National Council for Behavioral Health and does not provide national baseline data on the four domains of interoperability that are outlined in the Interoperability Roadmap (finding, sending, receiving and integrating data into EHRs) for behavioral health care providers. Currently, these providers are not eligible to participate in interoperability driving efforts such as the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) initiative. However, some behavioral health providers may be eligible in the future to participate in value-based payment initiatives such as the Merit-Based Incentive Payment System (MIPS). Measuring and reporting the state of interoperability will help to determine the type of support these providers need and their readiness to

participate in delivery system reform efforts in the future.

Collaboration between the Office of the National Coordinator for Health Information Technology (ONC) and SAMHSA on this data collection effort will provide an efficient manner to track trends in health IT adoption, use, and interoperability among behavioral health care providers. In addition, this collaboration will contribute to the development of strategic efforts to leverage health IT in behavioral health care settings to provide cost effective, high quality and patient-centered care. Results from this testing will allow ONC and SAMHSA to work together to quantitatively assess health IT adoption and interoperability among behavioral

health care providers using SAMHSA's current national surveys, the National Survey of Substance Abuse Treatment Services (N-SSATS) and the National Mental Health Services Survey (N-MHSS).

The information obtained from these efforts will be used to develop a new set of questions on the use and implementation of EHRs in behavioral health facilities for the N-SSATS and the N-MHSS surveys. Specifically, the information from the testing will be used to reduce respondent burden while simultaneously improving the quality of the data collected in these surveys.

Data from this testing will be collected mostly via telephone interviews, and few cases conducted

with in-person interviews. Results of this test will not be disseminated or used to inform policy, program, or budget decisions. Findings will be shared between ONC and SAMHSA staff to decide how the tested questions will be incorporated in the surveys.

It is estimated that the total burden for this project is 40 hours, based on a maximum of 80 interviews with an average of 30 minutes per interview.

The request for OMB seeks approval to conduct this testing of EHR questions during the Fall of 2018 for possible implementation starting in 2020.

The total estimated burden for this study is 39.2 hours for the period from September through December 2018.

Survey	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Interviews	80	1	80	.50	40

Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57-B, Rockville, MD 20857 OR email a copy at summer.king@samhsa.hhs.gov. Written comments should be received by September 25, 2018.

Summer King,
Statistician.

[FR Doc. 2018-16046 Filed 7-26-18; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the

information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Survey of Substance Abuse Treatment Services (N-SSATS) (OMB No. 0930-0106)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting a revision of the National Survey of Substance Abuse Treatment (N-SSATS) data collection (OMB No. 0930-0106), which expires on December 31, 2018. N-SSATS provides both national and state-level data on the numbers and types of patients treated and the characteristics of facilities providing substance abuse treatment services. It is conducted under the authority of Section 505 of the Public Health Service Act (42 U.S.C. 290aa-4) to meet the specific mandates for annual information about public and private substance abuse treatment providers and the clients they serve.

This request includes:

- Collection of N-SSATS, which is an annual survey of substance abuse treatment facilities; and
- Updating of the Inventory of Behavioral Health Services (I-BHS) which is the facility universe for the N-SSATS as well as the annual survey of

mental health treatment facilities, the National Mental Health Services Survey (N-MHSS). The I-BHS includes all substance abuse treatment and mental health treatment facilities known to SAMHSA. (The N-MHSS data collection is covered under OMB No. 0930-0119.)

The information in I-BHS and N-SSATS is needed to assess the nature and extent of these resources, to identify gaps in services, and to provide a database for treatment referrals. Both I-BHS and N-SSATS are components of the Behavioral Health Services Information System (BHSIS).

The request for OMB approval will include a request to update the I-BHS facility listing on a continuous basis and to conduct the N-SSATS and the between cycle N-SSATS (N-SSATS BC) in 2019, 2020, and 2021. The N-SSATS BC is a procedure for collecting services data from newly identified facilities between main cycles of the survey and will be used to improve the listing of treatment facilities in the online Behavioral Health Treatment Services Locator.

Planned Changes

I-BHS: Only minor form changes corresponding with updated technology are planned.

N-SSATS: The N-SSATS with client counts will continue to be conducted in alternate years, as in the past, and the Treatment Locator will be updated monthly.

Version A (2019 and 2021)

The following items have been added compared to the 2017 N-SSATS:

Add questions about: Where clients obtain their medications for opioid use disorder if they originate elsewhere; how facilities treat alcohol use disorder; where clients obtain their medications for alcohol use disorder if they originate elsewhere; whether the facility only treats alcohol use disorder; detoxification from opioids of abuse with lofexidine or clonidine; the percent of clients on MAT for opioid use disorder that receive maintenance services, detoxification, and relapse prevention; testing for metabolic syndrome; drug and alcohol oral fluid testing; professional interventionist/educational consultant; recovery coach; vocational training or educational support; Naloxone and overdose education; “Outcome follow-up after discharge” which was moved from another question; medications for HIV treatment; medications for Hepatitis C treatment; the medications lofexidine and clonidine; Hepatitis A and B vaccinations; Buprenorphine (*extended-release, injectable, for example, Sublocade®*); clients with co-occurring pain and substance use; Federally Qualified Health Centers (FQHC); Disulfiram, Naltrexone, or Acamprosate for alcohol use disorder for outpatient, inpatient, and residential. Also, response categories were added to select that services are not provided, and for medication services provided, an “other” category was added.

The following items have been deleted compared to the 2017 N-SSATS: Questions about religious affiliation, standard operating procedures, outpatient capacity, how (paper/electronic/both) a facility performs selected activities, and the item asking about Access To Recovery (ATR) client payments have been deleted.

The following additional changes have been made compared to the 2017 N-SSATS: Removed the asterisk from

the question about primary focus of facilities, which means the information will no longer be published on the N-SSATS treatment locator; reorganized the question about services offered; moved the question on types of counseling to the question about services offered; changed the wording from Screening for Hepatitis B and C to Testing for Hepatitis B and C; changed “Screening for mental health disorders” to “Screening for mental disorders”; changed the question about clinical/therapeutic approaches to a “mark all that apply” format; changed the wording from “Computerized substance abuse treatment/telemedicine” to “Telemedicine/telehealth”; changed the question wording about the number of outpatient clients so it states, “As of March 29, 2019, how many active clients were receiving each of the following outpatient substance abuse services at this facility?” and changed the instructions to state “An active client is a client who received treatment in March and is still enrolled in treatment on March 29, 2019.”; and changed the question about halfway houses so it states, “Does this facility operate transitional housing, a halfway house, or a sober home for substance abuse clients at this location, that is, the location listed on the front cover?”

For the question about how facilities treat opioid use disorder, information was added about the question that states, “For this question, MAT refers to any or all of these medications unless specified.” Also, category 5 was reworded to say “This facility administers naltrexone to treat opioid use disorder. Naltrexone use is authorized through any medical staff who have prescribing privileges.” In addition, a category was added, “This facility prescribes buprenorphine to treat opioid use disorder. Buprenorphine use is authorized through a DATA 2000 waived physician, physician assistant, or nurse practitioner.” Finally, for the last option, the wording was changed to “This facility is a *federally-certified*

Opioid Treatment Program (OTP). (Most OTPs administer/dispense methadone; some only use buprenorphine.)”

Version B (2020)

All changes to the 2019 N-SSATS were made for the 2020 N-SSATS except: Add the question asking if a facility is part of an organization with multiple facilities or sites, and if applicable, the question asking information about the parent site; remove the question about the percent of clients on MAT for opioid use disorder that receive maintenance services, detoxification, and relapse prevention; All of Section B (Reporting Client Counts) has been deleted which includes: How the facility will complete client counts; number of facilities in client counts; names and addresses of additional facilities reported for; number of hospital inpatient client counts by category, by number under age 18, number receiving methadone, buprenorphine, or naltrexone, and number of dedicated beds; number of residential client counts by category, by number under age 18, and number receiving methadone, buprenorphine, or naltrexone; type of substance abuse problem, percent of co-occurring clients; and 12-month admissions; remove questions about how many hospital inpatients, residential clients, and outpatient clients received Disulfiram, Naltrexone, and Acamprosate for alcohol use disorder; and add several new electronic health record questions.

N-SSATS (Between Cycles—BC)

The same changes to the 2020 N-SSATS (Version B) are requested for the N-SSATS BC except the electronic health record questions will not be added.

Estimated annual burden for the BHSIS activities is shown below:

Type of respondent and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
STATES:					
I-BHS Online ¹	56	75	4,200	0.08	336
State Subtotal	56	4,200	336
FACILITIES:					
I-BHS application ²	800	1	800	0.08	64
Augmentation screener	1,300	1	1,300	0.08	104
N-SSATS questionnaire	17,000	1	17,000	0.66	11,333
N-SSATS BC	1,000	1	1,000	0.58	580
Facility Subtotal	20,100	20,100	12,081

Type of respondent and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Total	20,156	24,300	12,417

¹ States use the I-BHS Online system to submit information on newly licensed/approved facilities and on changes in facility name, address, status, etc.

² New facilities complete and submit the online I-BHS application form in order to get listed on the Inventory.

Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fisher Lane, Room 15E57B, Rockville, MD 20852 OR email a copy at summer.king@samhsa.hhs.gov. Written comments should be received by September 25, 2018.

Summer King,
Statistician.

[FR Doc. 2018-16045 Filed 7-26-18; 8:45 am]

BILLING CODE 4162-20-P

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Notice of Amendments to the Program Comment for the U.S. General Services Administration on Select Envelope and Infrastructure Repairs and Upgrades to Historic Public Buildings

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice.

SUMMARY: The Advisory Council on Historic Preservation (ACHP) has approved amendments to the Program Comment for the U.S. General Services Administration (GSA) that sets forth the way in which GSA complies with Section 106 of the National Historic Preservation Act for select repairs and upgrades to windows, lighting, roofing, and heating, ventilating, and air conditioning (HVAC) systems within historic public buildings. The amendments extend the life of the Program Comment through August 1, 2033, and update its reporting requirements.

DATES: The amendments took effect on July 27, 2018.

ADDRESSES: Address any questions concerning the amendments to Kirsten Kulis, Office of Federal Agency Programs, Advisory Council on Historic Preservation, 401 F Street NW, Suite 308, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Kirsten Kulis, (202) 517-0217, kkulis@achp.gov.

SUPPLEMENTARY INFORMATION: Section 106 of the National Historic Preservation Act requires federal agencies to consider the effects of their undertakings on historic properties and

to provide the Advisory Council on Historic Preservation (ACHP) a reasonable opportunity to comment with regard to such undertakings. The ACHP has issued the regulations that set forth the process through which Federal agencies comply with these duties. Those regulations are codified under 36 CFR part 800 (Section 106 regulations).

Under Section 800.14(e) of those regulations, agencies can request the ACHP to provide a "Program Comment" on a particular category of undertakings in lieu of conducting individual reviews of each individual undertaking under such category, as set forth in 36 CFR 800.4 through 800.7. An agency can meet its Section 106 responsibilities with regard to the effects of particular aspects of those undertakings by taking into account an applicable Program Comment and following the steps set forth in that comment.

On August 7, 2009, the ACHP issued such a Program Comment, for use by the General Services Administration (GSA), regarding repairs and upgrades to windows, lighting, roofing, and heating, ventilating, and air conditioning. Under the Program Comment, such repairs are undertaken using GSA's Technical Preservation Guidelines (<https://www.gsa.gov/node/80914>), and are limited to those that do not adversely affect the qualities that qualify a subject historic building for listing in the National Register of Historic Places.

That Program Comment was set to expire on August 1, 2018. Earlier this year, GSA requested the ACHP to extend its term for fifteen (15) years, until August 1, 2033, and to de-couple its reporting requirements from those that occur under Section 3 of Executive Order 13287.

In late May 2018, after GSA requested consideration of such amendments, the ACHP held a conference call with the National Conference of State Historic Preservation Officers and the National Park Service (Technical Preservation Services). In late June 2018, ACHP emailed its members and other stakeholders requesting comments. Perhaps given the limited nature of the Program Comment itself and the straightforwardness of the proposed amendments, ACHP did not receive any substantive comments. The non-

substantive comments received were incorporated and are reflected in final amended version (see below).

The ACHP membership voted unanimously to adopt the mentioned amendments on July 20, 2018.

What follows is the text of the Program Comment, incorporating the adopted amendments:

Program Comment for General Services Administration Repairs and Upgrades to Windows, Lighting, Roofing, and Heating, Ventilating, and Air-Conditioning (HVAC), as Amended

I. Establishment and Authority: This Program Comment was issued by the Advisory Council on Historic Preservation (ACHP) as "Program Comment for General Services Administration Repairs and Upgrades to Windows, Lighting, Roofing, and Heating, Ventilating, and Air-Conditioning (HVAC)" on August 7, 2009, pursuant to 36 CFR 800.14(e). It provides the General Services Administration (GSA) with an alternative way to comply with its responsibilities under Section 106 of the National Historic Preservation Act, 54 U.S.C. 306108, and its implementing regulations, 36 CFR part 800 (Section 106), with regard to the effects of repairs and upgrades to windows, lighting, roofing, and heating, ventilating and air conditioning (HVAC) systems (Repairs/Upgrades) that follow the appended GSA Technical Preservation Guidelines (Guidelines). The appended Guidelines have been reviewed by the National Park Service, which confirms that they are in keeping with the Secretary of the Interior's Standards on Rehabilitation. This Program Comment was amended in July 2018 to, among other things, extend its duration to August 1, 2033.

II. Applicability to General Services Administration: Only GSA may use this Program Comment.

III. Date of Effect: This Program Comment went into effect on August 7, 2009 and was amended in July 2018.

IV. Use of This Program Comment To Comply With Section 106 Regarding the Effects of the Repairs and Upgrades:

(1) GSA may comply with Section 106 regarding the effects of Repairs/Upgrades on historic properties by:

(i) Making a determination that the proposed Repair/Upgrade may not adversely affect a historic property;

(ii) Notifying the relevant State Historic Preservation Officer (SHPO), through use of the notice form appended to this Program Comment that it intends to carry out a Repair/Upgrade:

(a) If, within 10 business days from receipt of the notification, the SHPO objects to the use of this Program Comment for the proposed Repair/Upgrade, GSA may not use the Program Comment for the proposed Repair/Upgrade. GSA will then comply with Section 106 for the proposed Repair/Upgrade in accordance with 36 CFR §§ 800.3 through 800.7 or any applicable alternative per 36 CFR 800.14.

(b) If the SHPO agrees with the proposed Repair/Upgrade, or does not object within 10 business days from receipt of the notification, GSA may proceed with the proposed Repair/Upgrade in accordance with this Program Comment;

(iii) Conducting such Repair/Upgrade as provided by the relevant Guidelines appended to this document;

(iv) Ensuring that all work on the Repair/Upgrade is designed by an architect and supervised and approved by a preservation professional, both of whom meet the relevant standards outlined in the Secretary of the Interior's Professional Qualification Standards, pursuant to 36 CFR part 61. In addition, the qualified supervisor will ensure construction phase preservation competency and quality control measures are implemented; and

(v) Keeping a record, at the relevant GSA office, detailing each use of this Program Comment for no less than five years from the final date of the implementation. Each record must include the following information:

(a) A description of the implementation of the Program Comment (including the specific location of the work);

(b) The date(s) when the Program Comment was implemented;

(c) The name(s) of the qualified personnel that carried out and/or supervised the use of the Program Comment; and

(d) A summary of the implementation, indicating how the Repair/Upgrade was carried out, any problems that arose, and the final outcome. GSA must provide copies of these records, within a reasonable timeframe, when requested by the ACHP or the relevant SHPO.

V. Discoveries: If previously unknown features are discovered while work under this Program Comment is being implemented (e.g., a mural behind plaster), GSA will notify SHPO of the

discovery and provide SHPO an opportunity to object to the use of this Program Comment, per Stipulation IV(l)(ii), above.

VI. Program Comment Does Not Cover Undertakings Involving Activities Beyond the Specific Repairs/Upgrades: The Repairs/Upgrades within the scope of this Program Comment will be discrete undertakings that do not include activities beyond the Repairs/Upgrades themselves. Among other things, the Repairs/Upgrades themselves will not include earth disturbing activities, new construction, site acquisition, change of occupancy or use, or alteration of exteriors or significant interior spaces.

VII. Process for Adding or Updating Repairs/Upgrades and Guidelines: While this Program Comment, as originally adopted, was limited to repairs and upgrades to historic building windows, lighting, roofing, and heating, ventilating and air conditioning (HVAC) systems undertaken in accordance with GSA Guidelines (Appendix B), more Repairs/Upgrades (and their relevant Guidelines) may be added to it. Moreover, Guidelines already included in the Program Comment may eventually need updating. Accordingly, Repairs/Upgrades and their Guidelines may be added to this Program Comment, or updated, as follows: (1) GSA will notify the ACHP, the National Conference of State Historic Preservation Officers (NCSHPO), and the Department of the Interior (DOI) (collectively, parties) that it wants to add an Upgrade/Guideline, or to update a Guideline that is already a part of the Program Comment. Such a notification will include a draft of the proposal. (2) The parties will consult on the proposal; and (3) If a final version of the proposal is approved by the ACHP Executive Director, the ACHP will publish a notice of availability of the approved addition or update in the **Federal Register**. The addition or update will go into effect as part of this Program Comment upon such publication.

VIII. Process for Removing a Repair/Upgrade and Its Guideline: After consulting with the parties, the ACHP may remove a Repair/Upgrade and its Guideline from the scope of this Program Comment by publishing a **Federal Register** notice to that effect. The Program Comment will continue to operate with the other Repairs/Upgrades and their Guidelines that have not been removed.

IX. GSA Option To Use Applicable Section 106 Agreements: If an existing Section 106 agreement applies to a proposed Repair/Upgrade, GSA may

follow either that existing agreement or this Program Comment.

X. Latest Version of the Program Comment: GSA and/or the ACHP will include the most current version of the Program Comment (with the latest amendments and updates) in a publicly accessible website. The latest Web address for that site will be included in each of the **Federal Register** notices for amending, removing or updating the Program Comment. This document and its 41 appended form and guidelines will initially be available at www.achp.gov and www.gsa.gov/historicpreservation.

XI. Reports: GSA will include in its reports under Section 3 of Executive Order 13287, or as separate reports submitted to the parties via electronic mail on or before the Section 3 reporting deadline, a summary of its experience implementing this Program Comment, how often and where the Program Comment has been utilized, examples of successful implementation, and examples of failures or problems with implementation.

XII. Amendment: The ACHP may amend this Program Comment (other than the appended Guidelines themselves, which are added, updated or removed according to Stipulations VII and VIII, above) after consulting with the parties and publishing a **Federal Register** notice to that effect.

XIII. Termination: The ACHP may terminate this Program Comment by publication of a notice in the **Federal Register** 30 days before the termination takes effect.

XIV. Sunset Clause: This Program Comment will terminate on its own accord on August 1, 2033, unless it is amended before that date to extend that period.

XV. Historic Properties of Significance to Indian Tribes and Native Hawaiian Organizations: This Program Comment does not apply in connection with effects to historic properties that are located on tribal lands and/or that are of religious and cultural significance to Indian tribes or Native Hawaiian organizations.

XVI. Definitions: The definitions found at 36 CFR part 800 apply to the terms used in this Program Comment.

XVII. Notification Form and GSA Technical Preservation Guidance Appendices:

Appendix A—GSA Program Comment Notification Form

GSA PROGRAM COMMENT NOTIFICATION FORM

I. General

Building name(s):

Address (city, state):
 Project title:
 Qualified Preservation Professional
 preparing report:
 Date:
 (Note: Qualified professionals must meet the relevant standards outlined in the Secretary of the Interior's Professional Qualification Standards, pursuant to 36 CFR part 61.)
 Location of work in the building:
 Project team (A/E Firm, Preservation Consultant, GSA Project Officer, Building Manager, and GSA Regional Historic Preservation Officer or Historic Preservation Program Staff Reviewer):

II. Scope and Purpose of Project (Bullets Are Acceptable)

III. Locations and Materials Affected (Check All That Apply)

Preservation Zones Affected (See Building Preservation Plan, Contact RHPO for Assistance.)

- Restoration
- Rehabilitation
- Renovation

Where does the project affect the historic property?

- Exterior
- Interior
- Lobbies/Vestibules
- Corridors
- Stairwells
- Elevators
- Restrooms
- Courtrooms
- Executive Suites
- General Office Space
- Other (specify)

What materials are affected by the project?

- Stone
- Brick
- Architectural Concrete
- Historic Roofing
- Bronze
- Architectural Metals (specify)
- Woodwork
- Ornamental Plaster
- Other (specify)

What assemblies are affected by the project?

- Windows and Skylights
- Doors
- Lighting
- Other (specify)

IV. Preservation Design Issues

List solutions explored, how resolved and why, such as (not inclusive):

- Locating new work/installation: Visibility, protection of ornamental finishes, cost concerns
- Design of new work/installation: Compatibility with existing original materials, research on original design (if original materials non-extant), materials/finishes chosen
- Method of supporting new work/installation
- Preservation and protection of historic materials

V. Graphics

- Include the following:
- Site or floor plan showing work location(s)

- Captioned photographs of existing site conditions in affected restoration zone locations
- Reduced project drawings, catalogue cut sheets or photographs showing solutions

VI. Confirmation

The undersigned hereby confirms and represents to the best of his or her knowledge and belief, the following as of this date: (1) The information in this form is correct; (2) GSA has determined that the proposed work will not adversely affect a historic property; (3) this project approach is consistent with the relevant GSA Technical Preservation Guidelines; (4) the design team includes a qualified preservation architect, engineer or conservator; (5) the design addresses construction phase preservation competency and quality control; and (6) this form will be submitted to the relevant SHPO for its review and opportunity for objection in a timely manner.

GSA Regional Historic Preservation Officer
 Signature:

Date:

Appendix B—GSA Technical Preservation Guidelines

(Please refer to <https://www.gsa.gov/node/80914> for a copy of the relevant guidelines. They are linked in that web page under the headings "Upgrading Historic Building Windows," "Upgrading Historic Building Lighting," "HVAC Upgrades in Historic Buildings," and "Historic Building Roofing.")

(END OF DOCUMENT)

Authority: 36 CFR 800.14(e).

Dated: July 24, 2018.

John M. Fowler,
 Executive Director.

[FR Doc. 2018–16104 Filed 7–26–18; 8:45 am]

BILLING CODE 4310-K6-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0110]

Agency Information Collection Activities: Visa Waiver Program Carrier Agreement

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

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The

information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted no later than September 25, 2018 to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0110 in the subject line and the agency name. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Email.* Submit comments to: CBP_PRA@cbp.dhs.gov.

(2) *Mail.* Submit written comments to CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE, 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number (202) 325–0056 or via email CBP_PRA@cbp.dhs.gov. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of

information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Visa Waiver Program Carrier Agreement.

OMB Number: 1651–0110.

Form Number: CBP Form I–775.

Current Actions: This submission is being made to extend the expiration date with a decrease in burden hours due to updated agency estimates on respondents. There is no change to information collected or to CBP Form I–775.

Type of Review: Extension (without change).

Abstract: Section 223 of the Immigration and Nationality Act (INA) (8 U.S.C. 1223(a)) provides for the necessity of a transportation contract. The statute provides that the Attorney General may enter into contracts with transportation lines for the inspection and administration of aliens coming into the United States from a foreign territory or from adjacent islands. No such transportation line shall be allowed to land any such alien in the United States until and unless it has entered into any such contracts which may be required by the Attorney General. Pursuant to the Homeland Security Act of 2002, this authority was transferred to the Secretary of Homeland Security.

The Visa Waiver Program Carrier Agreement (CBP Form I–775) is used by carriers to request acceptance by CBP into the Visa Waiver Program (VWP). This form is an agreement whereby carriers agree to the terms of the VWP as delineated in Section 217(e) of the INA (8 U.S.C. 1187(e)). Once participation is granted, CBP Form I–775 serves to hold carriers liable for the transportation costs, to ensure the completion of required forms, and to share passenger data. Regulations are promulgated at 8 CFR part 217.6, Carrier Agreements. A copy of CBP Form I–775 is accessible at: <http://www.cbp.gov/newsroom/publications/forms?title=775>.

Affected Public: Businesses.

Estimated Number of Respondents: 98.

Estimated Number of Total Annual Responses: 98.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 49.

Dated: July 24, 2018.

Seth D Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2018–16063 Filed 7–26–18; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Intent To Request Approval From OMB of One New Public Collection of Information: Law Enforcement Officers (LEOs) Flying Armed

AGENCY: Transportation Security Administration, DHS.

ACTION: 60-Day notice.

SUMMARY: The Transportation Security Administration (TSA) invites public comment on a new Information Collection Request (ICR) abstracted below that we will submit to the Office of Management and Budget (OMB) for approval in compliance with the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection involves gathering information from state, local and tribal armed law enforcement officers (LEOs) who require specialized screening at the checkpoint.

DATES: Send your comments by September 25, 2018.

ADDRESSES: Comments may be emailed to TSAPRA@tsa.dhs.gov or delivered to the TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh at the above address, or by telephone (571) 227–2062.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at <http://www.reginfo.gov> upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Consistent with the requirements of Executive Order (E.O.) 13771, Reducing Regulation and Controlling Regulatory Costs, and E.O. 13777, Enforcing the Regulatory Reform Agenda, TSA is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

Information Collection Requirement

TSA has broad statutory authority to assess a security risk for any mode of transportation, develop security measures for dealing with that risk, and enforce compliance with those measures.¹

TSA's mission includes the screening of individuals, accessible property, checked baggage, and cargo before boarding or loading on an aircraft to prevent or deter the carriage of any explosive, incendiary, or deadly or dangerous weapon on an aircraft. Under 49 CFR 1540.107, individuals are required to submit to screening and inspection before entering a sterile area of an airport or boarding an aircraft. The prohibition on carrying a weapon, however, does not apply to LEOs required to carry a firearm or other weapons while in the performance of law enforcement duties at the airport. See 49 CFR 1540.111(b). In addition, LEOs may fly armed if they meet the requirements of 49 CFR 1544.219. This section includes requirements for authorization to carry the weapon; training for flying armed; validation of the need for the weapon; notification requirements; prohibition related to consuming alcohol, and appropriation location of the weapon.

TSA has established a specialized screening process for State, local, and tribal LEOs when they are flying armed and need to go through screening at the checkpoint. When this situation will occur, LEOs are required to complete

¹ See 49 U.S.C. 114.

TSA Form 413A, Checkpoint Sign-In Log.

Purpose and Description of Data Collection

The information collected on TSA Form 413A includes identifying information on the LEOs; an affirmation that they are authorized to fly armed on official business and that they have an operational need to have their weapon accessible during the flight in accordance with 49 CFR part 1544; and identification of weapons they are carrying.

The information required by this form is used by the TSA Security Operations Center and the Law Enforcement/Federal Air Marshals Service in order to have situational awareness of armed law enforcement officer(s) presence on flights conducted by 49 CFR parts 1544 and/or 1546 regulated parties (aircraft operators and foreign air carriers). This real-time situational awareness is necessary in the event of a contingency on board the aircraft; such as but not limited to, a disruptive passenger, air piracy, or other threat to the safety and security of a commercial aircraft.

Respondents to this collection are State, local, and tribal police officers travelling with their weapons. TSA uses historical data to estimate 68,000 average annual responses. Each check-in requires filling out a log book and TSA estimates this activity requires one minute (0.0167 hours) to complete. TSA estimates this collection will place an annual average hour burden of 1,133 hours on the public.

Use of Results

TSA will use the information to have situational awareness of the presence of armed LEOs on flights conducted by 49 CFR parts 1544 and/or 1546 regulated parties (aircraft operators and foreign air carriers).

Dated: July 23, 2018.

Christina A. Walsh,

*TSA Paperwork Reduction Act Officer,
Information Technology.*

[FR Doc. 2018-16042 Filed 7-26-18; 8:45 am]

BILLING CODE 9110-05-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVL00000. L51100000.GN0000.
LVEMF1604790. 241A.18X; MO#4500101127]

**Notice of Availability for the Final
Environmental Impact Statement for
the Proposed Gold Rock Mine Project,
White Pine County, Nevada**

AGENCY: Bureau of Land Management,
Interior.

ACTION: Notice of Availability for the
Final Environmental Impact Statement
for the Proposed Gold Rock Mine
Project, White Pine County, Nevada.

SUMMARY: In accordance with the
National Environmental Policy Act of
1969, as amended (NEPA), and the
Federal Land Policy and Management
Act of 1976, as amended, the Bureau of
Land Management (BLM) Bristlecone
Field Office, Ely, Nevada, has prepared a
Final Environmental Impact Statement
(EIS) for the Gold Rock Mine Project
(Project), White Pine County, Nevada,
and by this notice is announcing its
availability.

DATES: The BLM will not issue a final
decision on the proposal for a minimum
of 30 days after the date that the
Environmental Protection Agency
publishes its Notice of Availability in
the **Federal Register**.

ADDRESSES: Copies of the Final EIS for
the Gold Rock Mine Project and other
documents pertinent to this proposal
may be examined at the Bristlecone
Field Office: 702 North Industrial Way,
Ely, Nevada. The document is available
for download on the internet at: [http://
on.doi.gov/1zAxyW9](http://on.doi.gov/1zAxyW9).

FOR FURTHER INFORMATION CONTACT:
Maria Ryan, Project Manager, (775) 289-
1888; mmryan@blm.gov. Persons who
use a telecommunications device for the
deaf (TDD) may call the Federal Relay
Service (FRS) at 1-800-877-8339 to
contact the above individual during
normal business hours. The FRS is
available 24 hours a day, 7 days a week,
to leave a message or question with the
above individual. You will receive a
reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Gold
Rock Mine Project would involve
construction and operation of an open-
pit gold mine on public land in White
Pine County, Nevada. Midway Gold
U.S. was the original proponent. GRP
Gold Rock, LLC Inc. (GRP) purchased
the project in 2016. The project would
involve expansion of an existing open
pit and construction of two waste rock
disposal areas, heap leaching facilities
with an adsorption/desorption refining

plant, a carbon-in-leach plant, a tailings
storage facility, roads, ancillary support
facilities, and exploration areas. A 69kV
power line would be built and tied into
an existing power line with the Pan
Mine located north of the project area.
Water with which GRP has rights would
be supplied via an existing well located
on BLM-administered lands south of the
main Project footprint. Construction and
mining operations would occur within
the fenced 8,757 acres and would
disturb 3,946 acres. The proposed action
also includes 200 acres of exploration
disturbance in addition to the 267 acres
of previously authorized exploration
outside the fenced area.

The Final EIS describes and analyzes
the proposed project site-specific
impacts (including cumulative effects)
on all affected resources. The Final EIS
describes eight alternatives: (1) The
Proposed Action; (2) the Northern
Power Line Route Alternative; (3) the
Southern Power Line Route Alternative;
(4) the Northwest Main Access Route
Alternative, Northern Power Line Route;
(5) the Northwest Main Access Route
Alternative, Southern Power Line Route;
(6) the Modified County Road Re-Route
Alternative; (7) the Western Tailings
Storage Facility Alternative; and (8) the
No Action Alternative.

1. Proposed Action

The proposed Project would be
constructed and operated in the same
geographic area as the reclaimed and
closed Easy Junior Mine. The proposed
Project consists of an open pit, two
waste rock disposal areas, a heap leach
pad and processing ponds, a carbon-in-
leach plant, a tailings storage facility,
haul and access roads, growth medium
stockpiles, ancillary support facilities,
and exploration associated with mining
operation. Also under the Proposed
Action, a 69-kV transmission line would
extend south from the Pan Mine, east of
and parallel to the approved Pan Mine
Southwest Power Line, then extend
southeast to the mine area. The site
would be accessed using the existing
main access route from US 50 on Green
Springs Road (CR 5), then west on BLM
Road 1179 (BLM 1179)/CR 1204, then
south on Easy Junior Road (CR 1177) to
the proposed mine area. Also under the
Proposed Action, a county road that
currently passes through the Gold Rock
Mine Project area would be re-located
onto existing and new BLM and county
roads. Total disturbance in the project
area would be approximately 3,946
acres.

2. Northern Power Line Route Alternative

The Northern Power Line Route Alternative was developed to minimize potential impacts to Greater sage-grouse and its habitat due to surface disturbance and from raptors using the power line between the Pan Mine and the Project as a perch to hunt for prey. This power line route would be shorter than the Proposed Action power line route. Fewer acres of Greater sage-grouse Priority Habitat Management Area (PHMA) and General Habitat Management Area (GHMA) would be disturbed and fewer acres of PHMA and GHMA would be located within 600 meters of the power line, as compared to the Proposed Action.

3. Southern Power Line Route Alternative

The Southern Power Line Route Alternative also was developed to minimize potential impacts to Greater sage-grouse and its habitat due to surface disturbance and from raptors using the power line as a perch to hunt for prey. This power line route would be shorter than Proposed Action power line route or the Northern Power Line Route Alternative. Fewer acres of PHMA and GHMA would be disturbed and fewer acres of PHMA and GHMA would be located within 600 meters of the power line, as compared to the Proposed Action power line or Northern Power Line Route Alternative.

4. Northwest Main Access Route Alternative, Northern Power Line Route

The Northwest Main Access Route Alternative, Northern Power Line Route was developed to address concerns about potential noise impacts to Greater sage-grouse. It would include the benefits of the Northern Power Line Route Alternative, and would move most mine-related traffic away from known active Greater sage-grouse leks. This alternative would also contribute to fewer potential vehicular collisions with big game due to its distance away from a known migration route for the Ruby Mountain mule deer herd.

5. Northwest Main Access Route Alternative, Southern Power Line Route

The Northwest Main Access Route Alternative, Southern Power Line Route was developed to address concerns about potential noise impacts to Greater sage-grouse. It would include the benefits of the Southern Power Line Route Alternative and would move most mine-related traffic away from known active Greater sage-grouse leks. This alternative would also contribute to fewer vehicular collisions with big game

due to its distance away from a known migration route for the Ruby Mountain mule deer herd.

6. Modified County Road Re-Route Alternative

The Modified County Road Re-route Alternative was developed to lessen impacts to GHMA. This alternative would involve use of existing roads rather than construction of a segment of new road in Greater sage-grouse habitat.

7. Western Tailings Storage Facility Alternative

The Western Tailings Storage Facility Alternative was developed to address concerns about potential surface disturbance impacts to PHMA and loss of mule deer crucial winter range. Under this alternative, the tailings storage facility would be located to the west of the heap leach pile, outside of mule deer crucial winter range. The mine area's eastern fence line would be shifted to the west to minimize restriction of movement for Ruby mule deer herd in their crucial winter range.

8. No Action Alternative

The No Action Alternative would not include any activities associated with the Proposed Action. Mineral resources in these areas of expansion would remain undeveloped. The construction and operation of the open pit, waste rock disposal areas, heap leach facilities, mill, tailings storage facility, and support facilities would not occur as currently proposed under the Proposed Action. The county road would not be re-routed. The exploration activities previously authorized under NVN-90376 for the project would continue, however. NEPA requires analysis of the No Action Alternative.

The BLM's Preferred Alternative is a combination of the Northwest Main Access Route Alternative, Southern Power Line Route (Alternative 5); the Modified County Road Re-route Alternative (Alternative 6); and the Western Tailings Storage Facility Alternative (Alternative 7). This Preferred Alternative would involve construction and operation of a shorter power line route than the Proposed Action by following the Southern Power Line Route. This power line would minimize surface disturbance impacts to PHMA and GHMA, as well as minimize potential raven and raptor predation of Greater sage-grouse. Total acres of surface disturbance in the Preferred Alternative are PHMA 1,872; GHMA 1,641.

In addition, the Preferred Alternative would use the Northwest Main Access Route, which would be located farther

from known active leks than the Proposed Action, minimizing potential noise impacts to Greater sage-grouse. This route could contribute to fewer vehicular collisions with big game due to its distance from a known migration route for Area 10 mule deer. The Preferred Alternative would use existing roads for the county road re-route as presented under the Modified County Road Re-route, minimizing new ground disturbance and impacts to GHMA.

The Preferred Alternative would incorporate the Western Tailings Storage Facility Alternative by shifting the tailings storage facility and related mine facility locations westward which would minimize surface disturbance in PHMA and mule deer crucial winter range and also would slightly increase the surface disturbance in GHMA.

The BLM identified action alternatives that would minimize impacts to the Greater sage-grouse, as well as mitigation measures to further avoid or minimize direct and indirect impacts PHMA and GHMA. In addition, the proponent committed to effective environmental protection measures, including mitigation measures to offset residual (long-term un-reclaimed) direct surface disturbance.

The BLM prepared the Draft EIS in conjunction with its four cooperating agencies: The Duckwater Shoshone Tribe of the Duckwater Reservation, Nevada; White Pine County Board of County Commissioners; Eureka County Board of Commissioners; and the Nevada Department of Wildlife (NDOW). After issuance of the Draft EIS, in accordance with a *Memorandum of Understanding between the BLM Nevada State Office and California State Office, and the Nevada Department of Conservation and Natural Resources, and the USFS Humboldt-Toiyabe National Forest* completed on April 1, 2016, the BLM added the Nevada Department of Conservation and Natural Resources Sagebrush Ecosystem Technical Team (SETT) as a fifth cooperating agency.

The BLM prepared and published a notice in the *Ely Times*, the *Eureka Sentinel*, the *High Desert Advocate*, and the *Reno Gazette-Journal* informing the public of the availability of the Draft EIS for review. The public was invited to provide written comments on the Draft EIS during the 45-day comment period. The BLM conducted public meetings in Ely, Eureka, and Reno during the review period for the Draft EIS.

A total of 26 individual comment submittals containing 253 discrete comments were received from the cooperating agencies, the public, the U.S. Environmental Protection Agency

(EPA), and the internal BLM review. The BLM considered all comments and incorporated them, as appropriate, into the FEIS. Those who submitted comments on the Draft EIS expressed concerns about the handling of leach solution and potentially acid-generating waste rock, and potential impacts to groundwater quality; loss of mule deer crucial winter range; potential impacts to Greater sage-grouse and their habitat; potential indirect impacts to the Railroad Valley springfish; loss of access to livestock grazing lands, including herding routes; long-term impacts to forage resource health in areas impacted by the proposed project; increased public accessibility to the area and impacts on private property; potential impacts on wild horses; potential impacts on Traditional Cultural Properties; socioeconomic impacts to the communities of Ely and Eureka, and to White Pine and Eureka counties; and particulate matter emissions and impacts to air quality. There were also comments received in general support for the mine. These public comments resulted in the addition of clarifying text, but did not significantly change the analysis. The proponent submitted a plan of operations for the Project in March 2013, and the BLM and EPA published notices of the availability of the Draft EIS in the **Federal Register** in February 2015. There have been several delays to completion of this Final EIS since 2013 due to sale of the mine, issuance of the Nevada and Northeast California Greater Sage-Grouse Land Use Plan Amendment (2015), and requests by the proponent to further address air quality concerns in 2016. The BLM has maintained on-going coordination and consultation with the Duckwater Shoshone Tribe. Both the BLM and GRP have committed to ongoing coordination through the life of the mine and have a Programmatic Agreement in place with the Nevada State Historic Preservation Office to address issues that arise.

Following a 30-day Final EIS availability and review period, the BLM will issue a Record of Decision (ROD). The decision reached in the ROD will be subject to appeal to the Interior Board of Land Appeals. The 30-day appeal period will begin with the issuance of the ROD.

Authority: 40 CFR 1506.6 and 40 CFR 1506.10.

Mindy Seal,

Field Manager, Bristlecone Field Office.

[FR Doc. 2018-16093 Filed 7-26-18; 8:45 am]

BILLING CODE 4310-HC-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAK940000.L14100000.BX0000.18X.LXSS001L0100]

Filing of Plats of Survey: Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of lands described in this notice are scheduled to be officially filed in the Bureau of Land Management (BLM), Alaska State Office, Anchorage, Alaska. The surveys, which were executed at the request of the U.S. Coast Guard, the Bureau of Indian Affairs and BLM, are necessary for the management of these lands.

DATES: Protests must be received by the BLM by August 27, 2018.

ADDRESSES: A copy of the plats may be obtained from the Alaska Public Information Center at the BLM Alaska State Office, 222 W 7th Avenue, Anchorage, Alaska 99513, upon required payment. The plats may be viewed at this location at no cost. Please use this address when filing written protests.

FOR FURTHER INFORMATION CONTACT:

Douglas N. Haywood, Chief, Branch of Cadastral Survey, Bureau of Land Management, Alaska State Office, 222 W. 7th Avenue, Anchorage, Alaska 99513; 1-907-271-5481; dhaywood@blm.gov. Persons who use a telecommunications device for the deaf may call the Federal Relay Service (FRS) at 1-800-877-8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lands surveyed are:

U.S. Survey No. 4901, accepted May 14, 2018.

Copper River Meridian, Alaska

T. 58 S., R. 78 E., accepted March 5, 2018
T. 58 S., R. 79 E., accepted March 5, 2018
T. 59 S., R. 78 E., accepted March 5, 2018
T. 59 S., R. 79 E., accepted March 5, 2018
T. 13 S., R. 7 W., accepted March 5, 2018

Fairbanks Meridian, Alaska

T. 6 S., R. 15 W., accepted March 27, 2018

Seward Meridian, Alaska

T. 18 N., R. 5 E., accepted January 5, 2018
T. 19 N., R. 5 E., accepted January 5, 2018
T. 20 N., R. 4 E., accepted January 5, 2018
T. 20 N., R. 7 E., accepted January 5, 2018
T. 21 N., R. 5 E., accepted January 5, 2018
T. 21 N., R. 6 E., accepted January 5, 2018

T. 22 N., R. 5 E., accepted January 5, 2018

T. 22 N., R. 6 E., accepted January 5, 2018

Kateel River Meridian, Alaska

T. 2 S., R. 40 W., accepted July 10, 2018

T. 3 S., R. 40 W., accepted July 10, 2018

Umiat Meridian, Alaska

T. 10 N., R. 2 E., accepted July 9, 2018

T. 10 N., R. 4 E., accepted July 9, 2018

T. 10 N., R. 5 E., accepted July 9, 2018

T. 11 N., R. 2 E., accepted July 9, 2018

T. 11 N., R. 3 E., accepted July 9, 2018

T. 11 N., R. 4 E., accepted July 9, 2018

A person or party who wishes to protest one or more plats of survey identified above must file a written notice of protest with the State Director for Alaska, BLM. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. The notice of protest must be filed before the scheduled date of official filing for the plat(s) of survey being protested. Any notice of protest filed after the scheduled date of official filing will not be considered. A notice of protest is considered filed on the date it is received by the State Director for Alaska during regular business hours; if received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of a protest, if not filed with the notice of protest, must be filed with the State Director for Alaska within 30 calendar days after the notice of protest is filed. If a notice of protest against a plat of survey is received prior to the scheduled date of official filing, the official filing of the plat of survey identified in the notice of protest will be stayed pending consideration of the protest. A plat of survey will not be officially filed until the dismissal or resolution of all protests of the plat.

Before including your address, phone number, email address, or other personal identifying information in a notice of protest or statement of reasons, you should be aware that the documents you submit, including your personal identifying information, may be made publicly available in their entirety at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. Chap. 3.

Douglas N. Haywood,

Chief Cadastral Surveyor, Alaska.

[FR Doc. 2018-16095 Filed 7-26-18; 8:45 am]

BILLING CODE 4310-HC-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On July 24, 2018, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of West Virginia in the lawsuit entitled *United States and West Virginia v. CSX Transportation, Inc.*, Civil Action No. 2:18-cv-01175.

The Complaint alleges that Defendant CSX Transportation, Inc., violated the Clean Water Act, the West Virginia Water Pollution Control Act, and the West Virginia Groundwater Protection Act by discharging oil into Armstrong Creek and the Kanawha River after Defendant's train derailed in February 2015 near Mount Carbon, West Virginia. The Consent Decree resolves the alleged violations through a settlement package with two components. First, the Consent Decree requires Defendant to pay a total civil penalty of \$2.2 million: \$1.2 million to resolve the United States' claims, and \$1 million to resolve West Virginia's claims. Second, Defendant must participate in a State supplemental environmental project ("State SEP") to settle West Virginia's claims only. The State SEP requires Defendant to pay \$500,000 into a State-created and State-owned escrow account that the State will use to fund upgrades to the Kanawha Falls Public Service District water treatment facility in Fayette County, West Virginia.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Acting Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and West Virginia v. CSX Transportation, Inc.*, Civil Action No. 2:18-cv-01175, DOJ number 90-5-1-1-11264. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	pubcomment-ees.enrd@usdoj.gov .
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: <https://www.justice.gov/enrd/consent-decrees>.

www.justice.gov/enrd/consent-decrees. We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Please enclose a check or money order for \$5.75 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the signature pages, the cost is \$4.25.

Robert Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2018-16087 Filed 7-26-18; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF LABOR

Office of the Secretary

Secretary's Order 05—2018

Subject: Procedures for Appointment of Individuals to Department of Labor Appellate Boards

1. *Purpose.* To provide for transparent and consistent processes by which the Secretary of Labor shall select and appoint individuals to the three appellate boards within the Department of Labor.

2. *Authorities and Directives Affected.*

A. Authorities. This Order is issued pursuant to the following authorities:

- i. 29 U.S.C. 551 *et seq.*;
- ii. 5 U.S.C. 301-02.

B. Directives Affected. This Order does not affect the authorities and responsibilities assigned by any other Secretary's Order, including but not limited to Order 02-2012 (77 FR 69378) and Order 03-2006 (20 CFR 801.201).

3. *Background.* The Secretary has the authority and responsibility to appoint the members of the Department's three appellate boards: the Administrative Review Board (ARB), the Benefits Review Board (BRB), and the Employees' Compensation Appeals Board (ECAB). These appointments should be made through a transparent and consistent process. Accordingly, this Order establishes procedures by which these appointments shall be made.

4. *Responsibilities.*

A. The Assistant Secretary for Administration and Management, in consultation with the Deputy Secretary, is assigned responsibility for issuing written guidance, as necessary, to implement this Order.

B. The Solicitor of Labor is responsible for providing legal advice to DOL on all matters arising in the implementation and administration of this Order.

5. *Procedure.* The following procedures shall apply to the selection and appointment of individuals to the ARB, BRB, and ECAB:

A. A notice of vacancy and solicitation of applications shall be posted in the **Federal Register** and on the relevant Board's website. The vacancy shall be held open for a minimum of thirty days, during which applications shall be accepted. The notice shall specify: The name of the board; the type of appointment; the duration, if any, of the appointment; the minimum criteria for appointment; the documentation an applicant must submit for consideration; the deadline by which such documentation must be submitted; and the email address and/or physical address where documentation may be submitted.

B. Applications will be directed to the Office of Executive Resources (OER) within the Office of the Assistant Secretary for Administration and Management (OASAM) to be screened for whether an applicant has timely submitted all required documentation and meets the minimal qualifications for the position, including vetting potential ethics concerns such as conflicts of interest in consultation with ethics counsel.

C. OER will deliver qualified applications to a six-person review panel. The members of the panel will be selected by the Secretary or the Secretary's designee,¹ and will consist of three career and three non-career Department employees who are members of the Senior Executive Service. The Department's Director, Human Resources Center, or her designee, shall be present for each meeting of the panel.

D. The panel will review the qualified applications, and rank the candidates. The panel will send the applications of the top-ranked candidates to an interview committee, which will be comprised of the Deputy Secretary and a career ethics attorney from Office of the Solicitor.

E. The interview committee will interview the top-ranked candidates and recommend to the Secretary which candidate should be chosen for the position. The interview committee will also provide the Secretary with the resumes of the other top-ranked candidates it interviewed but did not

¹ In the absence of specific Secretary's designee, the Solicitor of Labor shall be the designee.

recommend. The Secretary shall make the final decision and appointment, or may instead order another candidate search be completed.

6. *Privacy.* This Order is subject to the applicable laws, regulations, and procedures concerning the privacy of applicants to federal government employment.

7. *Exceptions.* The requirements of this Order are intended to be general in nature, and accordingly shall be construed and implemented consistent with more specific requirements of any statute, Executive Order, or other legal authority governing a particular board. In the event of a conflict, the specific statute, Executive Order, or other legal authority shall govern.

8. *Redelegation of Authority.* Except as otherwise provided by law, all of the authorities delegated in this Order may be redelegated in order to serve the purposes of this Order.

9. *Effective Date.* This order is effective immediately.

Dated: June 1, 2018.

R. Alexander Acosta,
Secretary of Labor.

[FR Doc. 2018-16127 Filed 7-26-18; 8:45 am]

BILLING CODE 4510-04-P

DEPARTMENT OF LABOR

Office of the Secretary

Procedures for Appointment of Individuals to Department of Labor Advisory Committees

Subject: Secretary's Order 04—2018

1. *Purpose.* To provide for transparent and consistent processes by which the Secretary of Labor and/or the designee of the Secretary of Labor shall select and appoint individuals to advisory committees¹ within the Department of Labor.

2. *Authorities and Directives Affected.*

A. *Authorities.* This Order is issued pursuant to the following authorities:

- i. 29 U.S.C. 551 *et seq.*;
- ii. 5 U.S.C. 301–02;
- iii. 5 U.S.C. app. 2, 1–15.

B. *Directives Affected.* This Order does not affect the authorities and responsibilities assigned by any other Secretary's Order.

3. *Background.* The Secretary and/or Secretary's designee has the authority and responsibility to appoint members of advisory committees that provide information, expertise, and recommendations to DOL agencies. These appointments should be made through a transparent and consistent process. Accordingly, this Order establishes procedures by which these appointments shall be made.

4. *Responsibilities.*

A. The Assistant Secretary for Administration and Management, in consultation with the Deputy Secretary, is assigned responsibility for issuing written guidance, as necessary, to implement this Order.

B. The Solicitor of Labor is responsible for providing legal advice to DOL on all matters arising in the implementation and administration of this Order.

5. *Procedure.* The following procedures shall apply to the selection and appointment of individuals to Department advisory committees for which the Secretary or the Secretary's designee is responsible:

A. A notice of vacancy and solicitation of applications shall be posted in the **Federal Register** and on the relevant committee or agency website. The vacancy shall be held open for a minimum of thirty days, during which applications shall be accepted. The notice shall specify: The name of the committee; the minimum requirements for committee membership, including specialized knowledge, experience, or other relevant criteria as mandated by the relevant statute, committee charter, or as determined by the agency administering the committee; the duration, if any, of the appointment; the minimum criteria for appointment; the documentation an applicant must submit for consideration; the deadline by which such documentation must be submitted; and the email address and/or physical address where documentation may be submitted.

B. Each application shall be directed to the relevant agency to be screened to determine whether the applicant has timely submitted all required documentation and meets the minimal qualifications for the position, including vetting the minimally qualified candidates for potential ethics concerns such as conflicts of interest in consultation with ethics counsel.

C. Qualified applications shall be reviewed by a panel established within the relevant agency. The members of each panel shall be selected by the head of the agency, and shall consist of six

employees who understand advisory committees and their functions. The Department's Director, Human Resources Center, or her designee, shall be present for each meeting of the panel. The panel shall select candidates it considers best meet the criteria for a specific committee. The committee shall send its proposed selections to the head of the agency, who shall review and provide the agency's recommendations to the Secretary and Deputy Secretary.

D. For an advisory committee that requires the Secretary himself make appointments, the Secretary shall make each final decision and appointment, or may instead order another candidate search be completed.

E. For an advisory committee that permits a Secretary's designee to make appointments, the Secretary, at his discretion, may review the recommendations himself pursuant to Paragraph 5.D of this order; or he may permit his designee to make the final decisions and appointments, or instead order another candidate search be completed, consistent with requirements of the applicable statute.

6. *Privacy.* This Order is subject to the applicable laws, regulations, and procedures concerning the privacy of applicants to federal government advisory committees.

7. *Exceptions; Administrative Matters.* The requirements of this Order are intended to be general in nature, and accordingly shall be construed and implemented consistent with more specific requirements of any statute, Executive Order, or other legal authority governing the composition of a particular advisory committee. In the event of a conflict, the specific statute, Executive Order, or other legal authority shall govern. The requirements of this Order are in addition to internal administrative procedures regarding the appointment of individuals to advisory committees.

8. *Redelegation of Authority.* Except as otherwise provided by law, all of the authorities delegated in this Order may be redelegated in order to serve the purposes of this Order.

9. *Date.* This order is effective immediately.

Dated: June 1, 2018.

R. Alexander Acosta,
Secretary of Labor.

[FR Doc. 2018-16124 Filed 7-26-18; 8:45 am]

BILLING CODE 4510-04-P

¹ "Committee" refers to any Federal Advisory Committee Act (FACA) advisory committee, committee, board, task force, or working group to which the Secretary of Labor or the designee of the Secretary appoints individuals. This Order does not apply to internal committees, boards, task forces, or working groups, or to purely interagency committees, boards, task forces, or working groups.

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION**[NARA-2018-051]****Agency Information Collection Activities: Proposed Collection; Comment Request****AGENCY:** National Archives and Records Administration (NARA).**ACTION:** Notice.

SUMMARY: NARA gives public notice that it proposes to request extension of three currently approved information collections. People use the first information collection to request permission to use privately owned equipment to digitize NARA and Presidential library archival holdings. They use the second information collection to request permission to film, photograph, or videotape at a NARA facility for news purposes. And they use the third information collection to request permission to use NARA facilities in the Washington, DC, area for events. We invite you to comment on these proposed information collections pursuant to the Paperwork Reduction Act of 1995.

DATES: We must receive written comments on or before September 25, 2018.

ADDRESSES: Send comments to Paperwork Reduction Act Comments (MP), Room 4100; National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740-6001, fax them to 301-837-0319, or email them to tamee.fechhelm@nara.gov.

FOR FURTHER INFORMATION CONTACT: Contact Tamee Fechhelm by telephone at 301-837-1694 or fax at 301-837-0319 with requests for additional information or copies of the proposed information collections and supporting statements.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13), NARA invites the public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for NARA to properly perform its functions; (b) NARA's estimate of the burden of the proposed information collection and its accuracy; (c) ways NARA could enhance the quality, utility, and clarity of the information it collects; (d) ways NARA could minimize the burden on respondents of

collecting the information, including through information technology; and (e) whether the collection affects small businesses. We will summarize any comments you submit and include the summary in our request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this notice, NARA solicits comments concerning the following information collections:

1. *Title:* Request to digitize records.

OMB number: 3095-0017.

Agency form number: None.

Type of review: Regular.

Affected public: Companies and organizations that wish to digitize archival holdings in the National Archives of the United States or a Presidential library for micropublication.

Estimated number of respondents: 10.

Estimated time per response: 5 hours.

Frequency of response: On occasion (when respondent wishes to request permission to digitize records).

Estimated total annual burden hours: 50.

Abstract: The information collection is prescribed by 36 CFR 1254.92. The collection is prepared by companies and organizations that wish to digitize archival holdings with privately-owned equipment. NARA uses the information to determine whether the request meets the criteria in 36 CFR 1254.94, to evaluate the records for digitization, and to schedule use of the limited space available for digitizing.

2. *Title:* Request to film, photograph, or videotape at a NARA facility for news purposes.

OMB number: 3095-0040.

Agency form number: None.

Type of review: Regular.

Affected public: Business or other for-profit, not-for-profit institutions.

Estimated number of respondents: 350.

Estimated time per response: 10 minutes.

Frequency of response: On occasion.

Estimated total annual burden hours: 58.

Abstract: The information collection is prescribed by 36 CFR 1280.48. The collection is prepared by organizations that wish to film, photograph, or videotape on NARA property for news purposes. NARA needs the information to determine if the request complies with NARA's regulations, to ensure protection of archival holdings, and to schedule the filming appointment.

3. *Title:* Request to use NARA facilities in the Washington, DC, area for events.

OMB number: 3095-0043.

Agency form number: None.

Type of review: Regular.

Affected public: Not-for-profit institutions, individuals or households, business or other for-profit, Federal Government.

Estimated number of respondents: 530.

Estimated time per response: Between 5 and 30 minutes.

Frequency of response: On occasion.

Estimated total annual burden hours: 169.

Abstract: The information collection is prescribed by 36 CFR 1280.80 and 1280.82. The collection is prepared by organizations that wish to use NARA public areas in the Washington, DC, area for an event. NARA uses the information to determine whether or not we can accommodate the request and to ensure that the proposed event complies with NARA regulations.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2018-16044 Filed 7-26-18; 8:45 am]

BILLING CODE 7515-01-P

POSTAL SERVICE**Temporary Emergency Committee of the Board of Governors; Sunshine Act Meeting**

TIME AND DATE: Wednesday, August 8, 2018, at 9:00 a.m.

PLACE: Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Wednesday, August 8, 2018, at 9:00 a.m.

1. Financial Matters.

2. Strategic Items.

3. Executive Session—Discussion of prior agenda items and Temporary Emergency Committee governance.

General Counsel Certification: The General Counsel of the United States Postal Service has certified that the meeting may be closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION:

Michael J. Elston, Acting Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260-1000. Telephone: (202) 268-4800.

Michael J. Elston,

Acting Secretary.

[FR Doc. 2018-16240 Filed 7-25-18; 4:15 pm]

BILLING CODE 7710-12-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83696; File No. 4–678]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17d–2; Notice of Filing and Order Approving and Declaring Effective an Amended Plan for the Allocation of Regulatory Responsibilities Among the Financial Industry Regulatory Authority, Inc., Miami International Securities Exchange, LLC, and MIAX PEARL, LLC

July 24, 2018.

Notice is hereby given that the Securities and Exchange Commission (“Commission”) has issued an Order, pursuant to Section 17(d) of the Securities Exchange Act of 1934 (“Act”),¹ approving and declaring effective an amendment to the plan for allocating regulatory responsibility (“Plan”) filed on June 28, 2018, pursuant to Rule 17d–2 of the Act,² by the Miami International Securities Exchange, LLC (“MIAX”), MIAX PEARL, LLC (“MIAX PEARL”), and the Financial Industry Regulatory Authority, Inc. (“FINRA”) (collectively, “Participating Organizations” or “parties”). This agreement amends and restates the agreement entered into between FINRA, MIAX, and MIAX PEARL on June 27, 2018, entitled “Agreement between Financial Industry Regulatory Authority, Inc., Miami International Securities Exchange, LLC and MIAX PEARL, LLC Pursuant to Rule 17d–2 under the Securities Exchange Act of 1934,” and any subsequent amendments thereafter.

I. Introduction

Section 19(g)(1) of the Act,³ among other things, requires every self-regulatory organization (“SRO”) registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO’s own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d)⁴ or Section 19(g)(2)⁵ of the Act. Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple

examinations of broker-dealers that maintain memberships in more than one SRO (“common members”). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

Section 17(d)(1) of the Act⁶ was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.⁷ With respect to a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d–1 and Rule 17d–2 under the Act.⁸ Rule 17d–1 authorizes the Commission to name a single SRO as the designated examining authority (“DEA”) to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO rules.⁹ When an SRO has been named as a common member’s DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d–1 deals only with an SRO’s obligations to enforce member compliance with financial responsibility requirements. Rule 17d–1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17d–2 under the Act.¹⁰ Rule 17d–2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect to their common members. Under paragraph (c) of Rule 17d–2, the Commission may declare such a plan effective if, after providing for

appropriate notice and opportunity for comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors, to foster cooperation and coordination among the SROs, to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system, and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17d–2 relieves an SRO of those regulatory responsibilities allocated by the plan to another SRO.

II. The Plan

On November 19, 2014, the Commission declared effective the Plan entered into between FINRA and MIAX for allocating regulatory responsibility pursuant to Rule 17d–2.¹¹ The Plan is intended to reduce regulatory duplication for firms that are common members of both MIAX and FINRA. The plan reduces regulatory duplication for firms that are members of MIAX and FINRA by allocating regulatory responsibility with respect to certain applicable laws, rules, and regulations. Included in the Plan is an exhibit that lists every MIAX rule for which FINRA bears responsibility under the Plan for overseeing and enforcing with respect to MIAX members that are also members of FINRA and the associated persons therewith (“Certification”). On January 12, 2017, the parties submitted a proposed amendment to the Plan to add MIAX PEARL as a Participant to the Plan.¹²

III. Proposed Amendment to the Plan

On June 28, 2018, the parties submitted a proposed amendment to the Plan (“Amended Plan”). The primary purpose of the Amended Plan is to allocate surveillance, investigation, and enforcement responsibilities for Rule 14e–4 under the Act, as well as certain provisions of Regulation SHO. The text of the proposed Amended Plan is as follows (additions are *underlined*; deletions are [bracketed]):

* * * * *

⁶ 15 U.S.C. 78q(d)(1).

⁷ See Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and Urban Affairs to Accompany S. 249, S. Rep. No. 94–75, 94th Cong., 1st Session 32 (1975).

⁸ 17 CFR 240.17d–1 and 17 CFR 240.17d–2, respectively.

⁹ See Securities Exchange Act Release No. 12352 (April 20, 1976), 41 FR 18808 (May 7, 1976).

¹⁰ See Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976).

¹¹ See Securities Exchange Act Release No. 73641 (November 19, 2014), 79 FR 70230 (November 25, 2014).

¹² See Securities Exchange Act Release No. 79974 (February 6, 2017), 82 FR 10417 (February 10, 2017).

¹ 15 U.S.C. 78q(d).

² 17 CFR 240.17d–2.

³ 15 U.S.C. 78s(g)(1).

⁴ 15 U.S.C. 78q(d).

⁵ 15 U.S.C. 78s(g)(2).

**AGREEMENT AMONG FINANCIAL INDUSTRY
REGULATORY AUTHORITY, INC.,
MIAMI INTERNATIONAL SECURITIES EXCHANGE, LLC AND MIAx PEARL, LLC
PURSUANT TO
RULE 17d-2 UNDER THE SECURITIES EXCHANGE ACT OF 1934**

This Agreement, by and among the Financial Industry Regulatory Authority, Inc. (“FINRA”), Miami International Securities Exchange, LLC (“MIAx”) and MIAx PEARL, LLC (“MIAx PEARL”), is made this [11th]27th day of [January, 2017]June, 2018 (the “Agreement”), pursuant to Section 17(d) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 17d-2 thereunder, which permits agreements between self-regulatory organizations to allocate regulatory responsibility to eliminate regulatory duplication. FINRA, MIAx and MIAx PEARL may be referred to individually as a “party” and together as the “parties.”

This Agreement amends and restates the agreement entered into between FINRA, [and] MIAx and MIAx PEARL on [October 13, 2014]January 11, 2017, entitled “Agreement between Financial Industry Regulatory Authority, Inc., [and] Miami International Securities Exchange, LLC and MIAx PEARL, LLC Pursuant to Rule 17d-2 under the Securities Exchange Act of 1934,” and any subsequent amendments thereafter.

WHEREAS, the parties desire to reduce duplication in the examination of their Common Members (as defined herein) and in the filing and processing of certain registration and membership records; and

WHEREAS, the parties desire to execute an agreement covering such subjects pursuant to the provisions of Rule 17d-2 under the Exchange Act and to file such agreement with the Securities and Exchange Commission (the “SEC” or “Commission”) for its approval.

NOW, THEREFORE, in consideration of the mutual covenants contained hereinafter, the parties hereby agree as follows:

1. **Definitions.** Unless otherwise defined in this Agreement or the context otherwise requires, the terms used in this Agreement shall have the same meaning as they have under the Exchange Act and the rules and regulations thereunder. As used in this Agreement, the following terms shall have the following meanings:
 - (a) “MIAX Rules,” “MIAX PEARL Rules” or “FINRA Rules” shall mean: (i) the rules of MIAX or MIAX PEARL, respectively, or (ii) the rules of FINRA, respectively, as the rules of an exchange or association are defined in Exchange Act Section 3(a)(27).
 - (b) “Common Rules” shall mean MIAX Rules and MIAX PEARL Rules that are substantially similar to the applicable FINRA Rules and certain provisions of the Exchange Act and SEC rules set forth on Exhibit 1 in that examination for compliance with such provisions and rules would not require FINRA to develop one or more new examination standards, modules, procedures, or criteria in order to analyze the application of the provision or rule, or a Common Member’s activity, conduct, or output in relation to such provision or rule. Common Rules shall not include any provisions regarding (i) notice, reporting or any other filings made directly to or from MIAX or MIAX PEARL, (ii) [compliance with other referenced]incorporation by reference of MIAX or MIAX PEARL Rules that are not Common Rules, (iii) exercise of discretion in a manner that differs from FINRA’s exercise of discretion including, but not limited to exercise of exemptive

authority, by MIAX or MIAX PEARL, (iv) prior written approval of MIAX or MIAX PEARL and (v) payment of fees or fines to MIAX or MIAX PEARL.

(c) “Common Members” shall mean members of FINRA and at least one of MIAX or MIAX PEARL.

(d) “Effective Date” shall be the date this Agreement is approved by the Commission.

(e) “Enforcement Responsibilities” shall mean the conduct of appropriate proceedings, in accordance with FINRA’s Code of Procedure (the Rule 9000 Series) and other applicable FINRA procedural rules, to determine whether violations of Common Rules have occurred, and if such violations are deemed to have occurred, the imposition of appropriate sanctions as specified under FINRA’s Code of Procedure and sanctions guidelines.

(f) “Regulatory Responsibilities” shall mean the examination responsibilities and Enforcement Responsibilities relating to compliance by the Common Members with the Common Rules and the provisions of the Exchange Act and the rules and regulations thereunder, and other applicable laws, rules and regulations, each as set forth on Exhibit 1 attached hereto. The term “Regulatory Responsibilities” shall also include the surveillance, investigation and Enforcement Responsibilities relating to compliance by Common Members with Rule 14e-4 of the Securities Exchange Act (“Rule 14e-4”), with a focus on the standardized call option provision of Rule 14e-4(a)(1)(ii)(D).

2. **Regulatory and Enforcement Responsibilities.** FINRA shall assume Regulatory Responsibilities and Enforcement Responsibilities for Common Members. Attached as

Exhibit 1 to this Agreement and made part hereof, MIAX and MIAX PEARL furnished FINRA with a current list of Common Rules and certified to FINRA that such rules that are MIAX Rules and MIAX PEARL Rules are substantially similar to the corresponding FINRA Rules (the “Certification”). FINRA hereby agrees that the rules listed in the Certification are Common Rules as defined in this Agreement. Each year following the Effective Date of this Agreement, or more frequently if required by changes in the rules of the parties, MIAX and MIAX PEARL shall submit an updated list of Common Rules to FINRA for review which shall add MIAX Rules or MIAX PEARL Rules not included in the current list of Common Rules that qualify as Common Rules as defined in this Agreement; delete MIAX Rules or MIAX PEARL Rules included in the current list of Common Rules that no longer qualify as Common Rules as defined in this Agreement; and confirm that the remaining rules on the current list of Common Rules continue to be MIAX Rules or MIAX PEARL Rules that qualify as Common Rules as defined in this Agreement. Within 30 days of receipt of such updated list, FINRA shall confirm in writing whether the rules listed in any updated list are Common Rules as defined in this Agreement. Notwithstanding anything herein to the contrary, it is explicitly understood that the term “Regulatory Responsibilities” does not include, and MIAX and MIAX PEARL shall retain full responsibility for (unless otherwise addressed by separate agreement or rule) (collectively, the “Retained Responsibilities”) the following:

- (a) surveillance, examination, investigation and enforcement with respect to trading activities or practices involving MIAX’s and MIAX PEARL’s own marketplace;
- (b) registration pursuant to their applicable rules of associated persons (i.e., registration rules that are not Common Rules);

-
- (c) discharge of their duties and obligations as a Designated Examining Authority pursuant to Rule 17d-1 under the Exchange Act; and
- (d) any MIAX Rules and MIAX PEARL Rules that are not Common Rules as provided in paragraph 6.
3. **Common Members.** Prior to the Effective Date, MIAX and MIAX PEARL shall furnish FINRA with a current list of Common Members, which shall be updated no less frequently than once each quarter.
4. **No Charge.** There shall be no charge to MIAX and MIAX PEARL by FINRA for performing the Regulatory Responsibilities and Enforcement Responsibilities under this Agreement except as hereinafter provided. FINRA shall provide MIAX and MIAX PEARL with ninety (90) days advance written notice in the event FINRA decides to impose any charges to MIAX and MIAX PEARL for performing the Regulatory Responsibilities under this Agreement. If FINRA determines to impose a charge, MIAX and MIAX PEARL shall have the right at the time of the imposition of such charge to terminate this Agreement; provided, however, that FINRA's Regulatory Responsibilities under this Agreement shall continue until the Commission approves the termination of this Agreement.
5. **Applicability of Certain Laws, Rules, Regulations or Orders.** Notwithstanding any provision hereof, this Agreement shall be subject to any statute, or any rule or order of the SEC. To the extent such statute, rule or order is inconsistent with one or more provisions of this Agreement, the statute, rule or order shall supersede the provision(s) hereof to the extent necessary to be properly effectuated and the provision(s) hereof in that respect shall be null and void.

6. **Notification of Violations.** In the event that FINRA becomes aware of apparent violations of any MIAX Rules or MIAX PEARL Rules, which are not listed as Common Rules, discovered pursuant to the performance of the Regulatory Responsibilities assumed hereunder, FINRA shall notify MIAX and MIAX PEARL of those apparent violations for such response as MIAX and MIAX PEARL deem appropriate. In the event that MIAX or MIAX PEARL becomes aware of apparent violations of any Common Rules, discovered pursuant to the performance of the Retained Responsibilities, MIAX and MIAX PEARL shall notify FINRA of those apparent violations and such matters shall be handled by FINRA as provided in this Agreement. Apparent violations of Common Rules shall be processed by, and enforcement proceedings in respect thereto shall be conducted by FINRA as provided hereinbefore; provided, however, that in the event a Common Member is the subject of an investigation relating to a transaction on MIAX or MIAX PEARL, MIAX and MIAX PEARL may in their discretion assume concurrent jurisdiction and responsibility. Each party agrees to make available promptly all files, records and witnesses necessary to assist the other in its investigation or proceedings.

7. **Continued Assistance.**

- (a) FINRA shall make available to MIAX and MIAX PEARL all information obtained by FINRA in the performance by it of the Regulatory Responsibilities hereunder with respect to the Common Members subject to this Agreement. In particular, and not in limitation of the foregoing, FINRA shall furnish MIAX and MIAX PEARL any information it obtains about Common Members which reflects adversely on their financial condition. MIAX and MIAX PEARL shall make available to FINRA any information coming to its attention that reflects

adversely on the financial condition of Common Members or indicates possible violations of applicable laws, rules or regulations by such firms.

(b) The parties agree that documents or information shared shall be held in confidence, and used only for the purposes of carrying out their respective regulatory obligations. No party shall assert regulatory or other privileges as against any other with respect to documents or information that is required to be shared pursuant to this Agreement.

(c) The sharing of documents or information among the parties pursuant to this Agreement shall not be deemed a waiver as against third parties of regulatory or other privileges relating to the discovery of documents or information.

8. **Statutory Disqualifications.** When FINRA becomes aware of a statutory disqualification as defined in the Exchange Act with respect to a Common Member, FINRA shall determine pursuant to Sections 15A(g) and/or Section 6(c) of the Exchange Act the acceptability or continued applicability of the person to whom such disqualification applies and keep MIAX and MIAX PEARL advised of its actions in this regard for such subsequent proceedings as MIAX and MIAX PEARL may initiate.
9. **Customer Complaints.** MIAX and MIAX PEARL shall forward to FINRA copies of all customer complaints involving Common Members received by MIAX and MIAX PEARL relating to FINRA's Regulatory Responsibilities under this Agreement. It shall be FINRA's responsibility to review and take appropriate action in respect to such complaints.
10. **Advertising.** FINRA shall assume responsibility to review the advertising of Common Members subject to the Agreement, provided that such material is filed with FINRA in

accordance with FINRA's filing procedures and is accompanied with any applicable filing fees set forth in FINRA Rules.

11. **No Restrictions on Regulatory Action.** Nothing contained in this Agreement shall restrict or in any way encumber the right of any party to conduct its own independent or concurrent investigation, examination or enforcement proceeding of or against Common Members, as any party, in its sole discretion, shall deem appropriate or necessary.
12. **Termination.** This Agreement may be terminated by any party at any time upon the approval of the Commission after one (1) year's written notice to the other parties (or such shorter time as agreed by the parties), except as provided in paragraph 4.
13. **Arbitration.** In the event of a dispute among the parties as to the operation of this Agreement, the parties hereby agree that any such dispute shall be settled by arbitration in Washington, D.C. in accordance with the rules of the American Arbitration Association then in effect, or such other procedures as the parties may mutually agree upon. Judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction. Each party acknowledges that the timely and complete performance of its obligations pursuant to this Agreement is critical to the business and operations of the other parties. In the event of a dispute among the parties, the parties shall continue to perform their respective obligations under this Agreement in good faith during the resolution of such dispute unless and until this Agreement is terminated in accordance with its provisions. Nothing in this Section 13 shall interfere with a party's right to terminate this Agreement as set forth herein.
14. **Separate Agreement.** This Agreement is wholly separate from the following agreement: (1) the multiparty Agreement made pursuant to Rule 17d-2 of the Exchange Act among BATS Exchange, Inc., BOX Options Exchange, LLC, Chicago Board Options Exchange,

Incorporated, C2 Options Exchange, Incorporated, the International Securities Exchange, LLC, FINRA, MIAx, NYSE MKT LLC, the NYSE Arca, Inc., The NASDAQ Stock Market LLC, NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, ISE Gemini, LLC, EDGX Exchange, Inc., [and] ISE Mercury, LLC and MIAx PEARL, LLC involving the allocation of regulatory responsibilities with respect to common members for compliance with common rules relating to the conduct by broker-dealers of accounts for listed options or index warrants entered as approved by the SEC on [February 16, 2016] February 2, 2017, and as may be amended from time to time; and (2) the multiparty Agreement made pursuant to Rule 17d-2 of the Exchange Act among NYSE MKT LLC, BATS Exchange, Inc., EDGX Exchange, Inc., BOX Options Exchange LLC, NASDAQ OMX BX, Inc., C2 Options Exchange, Incorporated, Chicago Board Options Exchange, Incorporated, International Securities Exchange LLC, ISE Gemini, LLC, ISE Mercury, LLC, FINRA, NYSE Arca, Inc., The NASDAQ Stock Market LLC, NASDAQ OMX PHLX, Inc., [and] MIAx and MIAx PEARL, LLC involving the allocation of regulatory responsibilities with respect to SRO market surveillance of common members activities with regard to certain common rules relating to listed options approved by the SEC on [February 16, 2016] February 2, 2017, and as may be amended from time to time.

15. **Notification of Members.** The parties shall notify Common Members of this Agreement after the Effective Date by means of a uniform joint notice.
16. **Amendment.** This Agreement may be amended in writing provided that the changes are approved by each party. All such amendments must be filed with and approved by the Commission before they become effective.

17. **Limitation of Liability.** None of the parties nor any of their respective directors, governors, officers or employees shall be liable to any other party to this Agreement for any liability, loss or damage resulting from or claimed to have resulted from any delays, inaccuracies, errors or omissions with respect to the provision of Regulatory Responsibilities as provided hereby or for the failure to provide any such responsibility, except with respect to such liability, loss or damages as shall have been suffered by any party and caused by the willful misconduct of another party or their respective directors, governors, officers or employees. No warranties, express or implied, are made by any party hereto with respect to any of the responsibilities to be performed by them hereunder.
18. **Relief from Responsibility.** Pursuant to Sections 17(d)(1)(A) and 19(g) of the Exchange Act and Rule 17d-2 thereunder, FINRA, MIAX and MIAX PEARL join in requesting the Commission, upon its approval of this Agreement or any part thereof, to relieve MIAX and MIAX PEARL of any and all responsibilities with respect to matters allocated to FINRA pursuant to this Agreement; provided, however, that this Agreement shall not be effective until the Effective Date.
19. **Severability.** Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.
20. **Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and such counterparts together shall constitute one and the same instrument.

* * * * *

EXHIBIT 1

Miami International Securities Exchange, LLC and MIAX PEARL, LLC Rules Certification for
17d-2 Agreement with FINRA

Miami International Securities Exchange, LLC (“MIAX”) and MIAX PEARL, LLC (“MIAX PEARL”) hereby certify that the requirements contained in the rules listed below are identical to, or substantially similar to, the comparable FINRA (NASD) Rule, Exchange Act provision or SEC rule identified (“Common Rules”).

[#]Common Rules shall not include any provisions regarding (i) notice, reporting or any other filings made directly to or from MIAX or MIAX PEARL, (ii) incorporation by reference of MIAX or MIAX PEARL Rules that are not Common Rules, (iii) exercise of discretion in a manner that differs from FINRA’s exercise of discretion including, but not limited to exercise of exemptive authority by MIAX or MIAX PEARL, (iv) prior written approval of MIAX or MIAX PEARL and (v) payment of fees or fines to MIAX or MIAX PEARL.

MIAX RULES	MIAX PEARL RULES	FINRA (NASD) RULES, EXCHANGE ACT PROVISION OR SEC RULE
Rule 301 Just and Equitable Principles of Trade ¹³	Rule 301 Just and Equitable Principles of Trade ¹	FINRA Rule 2010 Standards of Commercial Honor and Principles of Trade[*]
Rule 303 Prevention of the Misuse of Material Nonpublic Information ^{1, #}	Rule 303 Prevention of the Misuse of Material Nonpublic Information ^{1, #}	Section 15(g) of the Exchange Act and FINRA Rule 3110(b)(1) Supervision
Rule 315 Anti-Money Laundering Compliance Program [#]	Rule 315 Anti-Money Laundering Compliance Program [#]	FINRA Rule 3310 Anti-Money Laundering Compliance Program
Rule 318(a) Manipulation	Rule 318(a) Manipulation	FINRA Rule 2020 Use of Manipulative, Deceptive or other Fraudulent Devices[*]
Rule 318(b) Manipulation	Rule 318(b) Manipulation	FINRA Rule 6140(d) Other Trading Practices
Rule 319 Forwarding of Proxy and Other Issuer-Related Materials	Rule 319 Forwarding of Proxy and Other Issuer-Related Materials	FINRA Rule 2251 Processing and Forwarding of Proxy and Other Issuer-Related Materials

¹³ FINRA shall only have Regulatory Responsibilities regarding the rule and not the interpretations and policies.

Rule 320 Trading Ahead of Research Reports	Rule 320 Trading Ahead of Research Reports	FINRA Rule 5280 Trading Ahead of Research Reports
Rule 800(a), (b) and (d) Maintenance, Retention and Furnishing of Books, Records and Other Information ^{1#}	Rule 800(a), (b) and (d) Maintenance, Retention and Furnishing of Books, Records and Other Information ^{1,#}	FINRA Rule 4511 General Requirements* and Section 17 of the Exchange Act and the rules thereunder [#]
Rule 1304 Continuing Education for Registered Persons [#]	Rule 1304 Continuing Education for Registered Persons [#]	FINRA Rule 1250(a)(1)-(4), (6) and (b) Continuing Education Requirements [#]
Rule 1321 Transfer of Accounts	Rule 1321 Transfer of Accounts	FINRA Rule 11870 Customer Account Transfer Contracts
Rule 1325 Telemarketing	Rule 1325 Telemarketing	FINRA Rule 3230 Telemarketing

In addition, the following provisions shall be part of this 17d-2 Agreement:

SEA Rule 200 of Regulation SHO – Definition of “Short Sale” and Marking Requirements and
SEA Rule 201 of Regulation SHO – Circuit Breaker

SEA Rule 203 of Regulation SHO – Borrowing and Delivery Requirements

SEA Rule 204 of Regulation SHO – Close-Out Requirement

SEA Rule 14e-4 – Prohibited Transactions in Connection with Partial Tender Offers[^]

[^]FINRA shall perform surveillance, investigation, and Enforcement Responsibilities for SEA Rule 14e-4(a)(1)(ii)(D).

[* FINRA shall not have Regulatory Responsibilities for these rules as they pertain to violations of insider trading activities, which is covered by a separate 17d-2 Agreement by and among BATS Exchange, Inc., BATS Y-Exchange, Inc., Chicago Board Options Exchange, Inc., Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, the NASDAQ Stock Market LLC, National Stock Exchange, Inc., New York Stock Exchange LLC, NYSE Amex LLC, and NYSE Arca Inc., effective December 16, 2011, as may be amended from time to time.]

[[#]FINRA shall not have Regulatory Responsibilities regarding (i) notice, reporting or any other filings made directly to or from MIAX or MIAX PEARL, (ii) compliance with other referenced MIAX or MIAX PEARL Rules that are not Common Rules, (iii) exercise of discretion including, but not limited to exercise of exemptive authority, by MIAX or MIAX PEARL, (iv) prior written approval of MIAX or MIAX PEARL and (v) payment of fees or fines to MIAX or MIAX PEARL.]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number 4–678 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.
- All submissions should refer to File Number 4–678. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed plan that are filed with the Commission, and all written communications relating to the proposed plan between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the plan also will be available for inspection and copying at the principal offices of FINRA, MIAx, and MIAx PEARL. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number 4–678 and should be submitted on or before August 17, 2018.

V. Discussion

The Commission finds that the proposed Amended Plan is consistent with the factors set forth in Section 17(d) of the Act¹⁴ and Rule 17d–2(c) thereunder¹⁵ in that the proposed Amended Plan is necessary or

appropriate in the public interest and for the protection of investors, fosters cooperation and coordination among SROs, and removes impediments to and fosters the development of the national market system. In particular, the Commission believes that the proposed Amended Plan should reduce unnecessary regulatory duplication by allocating to FINRA certain examination and enforcement responsibilities for Common Members that would otherwise be performed by FINRA and MIAx or MIAx PEARL. Accordingly, the proposed Amended Plan promotes efficiency by reducing costs to Common Members. Furthermore, because MIAx, MIAx PEARL, and FINRA will coordinate their regulatory functions in accordance with the Amended Plan, the Amended Plan should promote investor protection.

The Commission notes that, under the Amended Plan, MIAx, MIAx PEARL, and FINRA have allocated regulatory responsibility for those MIAx and MIAx PEARL rules, set forth in the Certification, that are substantially similar to the applicable FINRA rules in that examination for compliance with such provisions and rules would not require FINRA to develop one or more new examination standards, modules, procedures, or criteria in order to analyze the application of the rule, or a Common Member's activity, conduct, or output in relation to such rule. In addition, under the Amended Plan, FINRA would assume regulatory responsibility for certain provisions of the federal securities laws and the rules and regulations thereunder that are set forth in the Certification. The Common Rules covered by the Amended Plan are specifically listed in the Certification, as may be amended by the parties from time to time.

According to the Amended Plan, MIAx and MIAx PEARL will review the Certification at least annually, or more frequently if required by changes in either the rules of MIAx, MIAx PEARL or FINRA, and, if necessary, submit to FINRA an updated list of Common Rules to add MIAx or MIAx PEARL rules not included on the then-current list of Common Rules that are substantially similar to FINRA rules; delete MIAx or MIAx PEARL rules included in the then-current list of Common Rules that no longer qualify as common rules; and confirm that the remaining rules on the list of Common Rules continue to be MIAx or MIAx PEARL rules that qualify as common rules.¹⁶ FINRA will then confirm in writing whether the rules listed in any

updated list are Common Rules as defined in the Amended Plan. Under the Amended Plan, MIAx and MIAx PEARL also will provide FINRA with a current list of Common Members and shall update the list no less frequently than once each quarter.¹⁷ The Commission believes that these provisions are designed to provide for continuing communication between the parties to ensure the continued accuracy of the scope of the proposed allocation of regulatory responsibility.

The Commission is hereby declaring effective an Amended Plan that, among other things, allocates regulatory responsibility to FINRA for the oversight and enforcement of all MIAx and MIAx PEARL rules that are substantially similar to the rules of FINRA for Common Members of FINRA and MIAx, and FINRA and MIAx PEARL. Therefore, modifications to the Certification need not be filed with the Commission as an amendment to the Amended Plan, provided that the parties are only adding to, deleting from, or confirming changes to MIAx or MIAx PEARL rules in the Certification in conformance with the definition of Common Rules provided in the Amended Plan. However, should the parties decide to add a MIAx or MIAx PEARL rule to the Certification that is not substantially similar to a FINRA rule; delete a MIAx or MIAx PEARL rule from the Certification that is substantially similar to a FINRA rule; or leave on the Certification a MIAx or MIAx PEARL rule that is no longer substantially similar to a FINRA rule, then such a change would constitute an amendment to the Amended Plan, which must be filed with the Commission pursuant to Rule 17d–2 under the Act.¹⁸

Under paragraph (c) of Rule 17d–2, the Commission may, after appropriate notice and comment, declare a plan, or any part of a plan, effective. In this instance, the Commission believes that appropriate notice and comment can take place after the proposed amendment is effective. The primary purpose of the amendment is to allocate surveillance, investigation, and enforcement responsibilities for Rule 14e–4 under the Act, as well as certain provisions of Regulation SHO. By declaring it effective today, the Amended Plan can become effective and

¹⁷ See paragraph 3 of the Amended Plan.

¹⁸ The addition to or deletion from the Certification of any federal securities laws, rules, and regulations for which FINRA would bear responsibility under the Amended Plan for examining, and enforcing compliance by, Common Members, also would constitute an amendment to the Amended Plan.

¹⁴ 15 U.S.C. 78q(d).

¹⁵ 17 CFR 240.17d–2(c).

¹⁶ See paragraph 2 of the Amended Plan.

be implemented without undue delay. The Commission notes that the prior version of this plan immediately prior to this proposed amendment was published for comment and the Commission did not receive any comments thereon.¹⁹ Furthermore, the Commission does not believe that the amendment to the plan raises any new regulatory issues that the Commission has not previously considered.

VI. Conclusion

This order gives effect to the Amended Plan filed with the Commission in File No. 4–678. The parties shall notify all members affected by the Amended Plan of their rights and obligations under the Amended Plan.

It is therefore ordered, pursuant to Section 17(d) of the Act, that the Amended Plan in File No. 4–678, between the FINRA, MIAX, and MIAX PEARL, filed pursuant to Rule 17d–2 under the Act, hereby is approved and declared effective.

It is further ordered that MIAX and MIAX PEARL are each relieved of those responsibilities allocated to FINRA under the Amended Plan in File No. 4–678.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–16110 Filed 7–26–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83687; File No. SR–NYSENAT–2018–16]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Schedule of Fees and Rebates To Adopt Two New Adding Tiers and Regulatory Fees in Connection With Use of the Central Registration Depository

July 23, 2018.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the “Act”)² and Rule 19b–4 thereunder,³ notice is hereby given that, on July 9, 2018, NYSE National, Inc. (“Exchange” or “NYSE National”) filed with the Securities and Exchange Commission

(“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Schedule of Fees and Rebates to adopt (1) two new adding tiers, and (2) regulatory fees in connection with use of the Central Registration Depository (“CRD”) by Exchange ETP Holders that are not also members of the Financial Industry Regulatory Authority, Inc. (“FINRA”). The Exchange proposes to implement the rule change on July 9, 2018.⁴ The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Schedule of Fees and Rebates to adopt (1) two new adding tiers, and (2) regulatory fees in connection with use of CRD.

The Exchange proposes to implement the rule change on July 9, 2018.

Proposed Adding Tiers

The Exchange proposes two new adding tiers for displayed and non-displayed orders in securities priced at or above \$1.00, as follows. Current

Adding Tier would be re-named “Adding Tier 1.”

Adding Tier 2

Under proposed Adding Tier 2, the Exchange would offer the following fees for transactions in stocks with a per share price of \$1.00 or more when adding liquidity to the Exchange if the ETP Holder quotes at least 5% of the NBBO⁵ in 1,000 or more symbols on an average daily basis, calculated monthly:

- \$0.0005 per share for adding displayed orders;
- \$0.0005 per share for orders that set a new Exchange BBO;
- \$0.0007 per share for adding non-displayed orders; and
- \$0.0005 per share for MPL orders.

For example, in a given month, if an ETP Holder quotes at least 5% of the NBBO in 800 symbols in round lots on the first day of the month and 1,400 symbols on the second day of the month, the ETP Holder would have 1,100 securities on average daily basis that meet the 5% NBBO requirement after the second day, and would qualify for the proposed Adding Tier 2 after the second day. Further, in a given symbol on a given day, if the ETP Holder maintains a bid at the NBB for 4% of the trading day and an offer at the NBO for 8% of the trading day, that would result in the ETP Holder quoting 6% of the NBBO in that symbol for that day and that symbol meeting the 5% NBBO requirement for that day.

Adding Tier 3

Under proposed Adding Tier 3, the Exchange would offer the following fees for transactions in stocks with a per share price of \$1.00 or more when adding liquidity to the Exchange if the ETP Holder quotes at least 5% of the NBBO⁶ in 600 or more symbols on an average daily basis, calculated monthly:

- \$0.0012 per share for adding displayed orders;
- \$0.0012 per share for orders that set a new Exchange BBO;
- \$0.0014 per share for adding non-displayed orders; and
- \$0.0005 per share for MPL orders.

Finally, as reflected in footnote * of the Schedule of Fees and Rebates, the volume requirements for the current

¹⁹ See *supra* note 12 (citing to Securities Exchange Act Release No. 79974).

²⁰ 17 CFR 200.30–3(a)(34).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

⁴ The Exchange originally filed to amend the Fee Schedule on June 27, 2018 (SR–NYSENAT–2018–14) and withdrew such filing on July 9, 2018. This filing replaces SR–NYSENAT–2018–14 in its entirety.

⁵ The Exchange would explain the proposed 5% requirement in a new footnote **. As proposed, ETP Holders would have to maintain a bid or an offer at the NBB or the NBO for at least 5% of the trading day in round lots in a security for that security to count toward the tier requirement. The terms “NBB,” “NBO,” “NBBO,” and “BBO” are defined in NYSE National Rule 1.1. The Exchange believes that the proposed 5% threshold is appropriate for a market of NYSE National’s size and trading volume.

⁶ See note 5, *supra*.

Adding Tier and the Taking Tier are waived until July 1, 2018. The Exchange proposes to extend the volume requirements [sic] for these tiers indefinitely. To effect this change, the Exchange would delete “until July 1, 2018” from footnote *. As noted, the current Adding Tier would be re-named “Adding Tier 1,” which will also be reflected in footnote *.

CRD Fees

The Exchange proposes to adopt regulatory fees related to CRD that would be collected by FINRA.⁷ As proposed, FINRA would collect and retain certain regulatory fees via CRD for the registration of persons associated with an Exchange ETP Holder that is not also a FINRA member. The CRD fees are use-based and there is no distinction in the cost incurred by FINRA if the user is a FINRA member or a member of an exchange but not a FINRA member. Accordingly, the Exchange proposes to adopt the following fees to mirror those assessed by FINRA pursuant to Section (4) of Schedule A to the FINRA By-Laws:⁸

(1) \$100 for each initial Form U4 filed for the registration of a representative or principal;

(2) \$110 for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification of one or more disclosure events or proceedings;

(3) \$15 for processing and posting to the CRD system each set of fingerprint cards submitted electronically by the Member, plus a pass-through of any other charge imposed by the United States Department of Justice for processing each set of fingerprints;

(4) \$30 for processing and posting to the CRD system each set of fingerprint cards submitted in non-electronic format by the Member, plus a pass-through of any other charge imposed by the United States Department of Justice for processing each set of fingerprints;

(5) \$30 for processing and posting to the CRD system each set of fingerprint results and identifying information that has been processed through another self-regulatory organization and submitted to FINRA; and

(6) \$45 annually for system processing for each registered representative and principal.

* * * * *

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that ETP Holders would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁹ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹⁰ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

New Adding Tiers

The Exchange believes that the proposed Adding Tier 2 and Adding Tier 3 fees for ETP Holder with at least 5% of the NBBO in 1,000 or more symbols on an average daily basis, calculated monthly or 600 or more symbols on an average daily basis, calculated monthly, respectively, who maintain a bid or an offer at the NBB or NBO in each assigned security in round lots averaging at least 5% of the trading day on an average daily basis, calculated monthly, in securities with a per share price of \$1.00 or more when adding liquidity are reasonable because the proposed tiers would further contribute to incentivizing ETP Holders to provide increased displayed liquidity on the Exchange, benefiting all ETP Holders. In addition, the Exchange believes that the proposed Adding Tier 2 and Adding Tier 3 fees are equitable and not unfairly discriminatory as all similarly situated market participants will be subject to the same fees on an equal and non-discriminatory basis. The Exchange further believes that providing the same fee for adding displayed orders as that for orders that set a new Exchange BBO under Adding Tier 2 and Adding Tier 3 is reasonable because the \$0.0005 and \$0.0012 fee per share in Adding Tier 2 and Adding Tier 3, respectively, are

sufficient incentive for providing liquidity.

Finally, the Exchange believes it is reasonable to indefinitely waive the Adding Tier (which would be re-named Adding Tier 1) and Taking Tier volume requirements because the waiver will enable the Exchange to continue to improve its overall competitiveness and strengthen its market quality for all market participants. The proposed waiver is not unfairly discriminatory because it will apply equally to all similarly situated ETP Holders.

CRD Fees

The proposed CRD fees are reasonable because they are identical to those adopted by FINRA for use of the CRD system for disclosure and the registration of associated persons of FINRA members.¹¹ As FINRA noted in its filing adopting its existing fees, FINRA believes the fees are reasonable based on the increased costs associated with operating and maintaining the CRD system, and listed a number of enhancements made to the CRD system since the last fee increase, including: (1) Incorporation of various uniform registration form changes; (2) electronic fingerprint processing; (3) Web EFT™, which allows subscribing firms to submit batch filings to the CRD system; (4) increases in the number and types of reports available through the CRD system; and (5) significant changes to BrokerCheck, including making BrokerCheck easier to use and expanding the amount of information made available through the system.¹² These increased costs are similarly borne by FINRA when an Exchange ETP Holder that is not a FINRA member uses the CRD system, so the fees collected for such use should, as proposed by the Exchange, mirror the fees assessed on FINRA members. FINRA further noted that the proposed fees are reasonable because they help to ensure the integrity of the information in the CRD system, which is important because the Commission, FINRA, other self-regulatory organizations and state securities regulators use the CRD system to make licensing and registration decisions, among other things.¹³

The Exchange similarly believes that the proposed fees, like FINRA's fees, are consistent with an equitable allocation of fees because the fees will apply equally to all individuals and firms required to report information to the

⁷ CRD is the central licensing and registration system for the U.S. securities industry. The CRD system enables individuals and firms seeking registration with multiple states and self-regulatory organizations to do so by submitting a single form, fingerprint card and a combined payment of fees to FINRA. Through CRD, FINRA maintains the qualification, employment and disciplinary histories of registered associated persons of broker dealers.

⁸ The proposed CRD fees are those charged by FINRA to non-FINRA members when such fees are applicable. The Exchange notes that there are certain FINRA CRD fees and requirements that are specific to FINRA members but do not apply to Exchange ETP Holders that are not also FINRA members. Exchange ETP Holders that are also FINRA members would be charged CRD fees according to Section (4) of Schedule A to the FINRA By-Laws.

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(4) & (5).

¹¹ See Securities Exchange Act Release No. 67247 (June 25, 2012), 77 FR 38866 (June 29, 2012) (SR-FINRA-2012-30).

¹² See *id.*, 77 FR at 38868.

¹³ *Id.*

CRD system. Thus, those members that register more individuals or submit more filings through the CRD system will generally pay more in fees than those that use the CRD system to a lesser extent. In addition, the proposed fees, like FINRA's fees, are equitable and not unfairly discriminatory because they will result in the same regulatory fees being charged to all ETP Holders required to report information to the CRD system and for services performed by FINRA, regardless of whether or not such ETP Holder is a FINRA member.

Further, the Exchange believes the proposed CRD fees provide for the equitable allocation of reasonable fees and other charges among its permit holders, and does not unfairly discriminate between customers, issuers, brokers and dealers. All similarly situated ETP Holders are subject to the same fee structure, and every Member firm must use the CRD system for registration and disclosure.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,¹⁴ the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities for ETP Holders. The Exchange believes that this could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive

with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As a result of all of these considerations, the Exchange does not believe that the proposed changes will impair the ability of ETP Holders or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)¹⁵ of the Act and subparagraph (f)(2) of Rule 19b-4¹⁶ thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹⁷ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSENAT-2018-16 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSENAT-2018-16. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSENAT-2018-16 and should be submitted on or before August 17, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-16023 Filed 7-26-18; 8:45 am]

BILLING CODE 8011-01-P

¹⁵ 15 U.S.C. 78s(b)(3)(A).

¹⁶ 17 CFR 240.19b-4(f)(2).

¹⁷ 15 U.S.C. 78s(b)(2)(B).

¹⁸ 17 CFR 200.30-3(a)(12).

¹⁴ 15 U.S.C. 78f(b)(8).

DEPARTMENT OF TRANSPORTATION**Federal Railroad Administration**

[Docket No. FRA–2017–0074, Notice No. 2; Safety Advisory 2018–01]

Addressing Electrode-Induced Rail Pitting From Pressure Electric Welding

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of Safety Advisory.

SUMMARY: FRA is issuing Safety Advisory 2018–01 to remind railroads, contractors, and the rail welding industry of the potential for electrode-induced rail pitting and fatigue cracking during the pressure electric rail welding process.

FOR FURTHER INFORMATION CONTACT: Mr. Matthew Brewer, Staff Director, Rail Integrity Division, Office of Railroad Safety, FRA, 500 Broadway, Suite 240, Vancouver, WA 98660, telephone (202) 385–2209; or Mr. Aaron Moore, Trial Attorney, Office of Chief Counsel, FRA, 1200 New Jersey Avenue SE, Washington, DC 20590, telephone (202) 493–7009.

SUPPLEMENTARY INFORMATION: On August 16, 2017, FRA published a notice of a draft safety advisory in the *Federal Register* to address electrode-induced rail pitting from pressure electric welding and seeking comment on the issue. 82 FR 38989. FRA noted its investigation and research into the issue demonstrated that improper electrode contact to the rail during the welding process could result in electrode-induced pitting that may lead to fatigue fracture and ultimately rail failure. As a result, FRA's draft safety advisory contained specific recommendations to help the industry prevent electrode-induced pitting.

FRA presented the information contained in the draft safety advisory to its Railroad Safety Advisory Committee's (RSAC) Rail Integrity Working Group. Subsequent RSAC discussions and comments submitted by the Association of American Railroads (AAR) indicated that the rail industry agrees with FRA's concern that stray arcing can result in the formation of electrode pits and that fatigue cracking can then develop from these electrode pits. AAR noted, however, that FRA's draft safety advisory did not present any information to support a finding that rail failures from electrode-induced rail pitting are a wide-spread problem. Further, AAR noted that its member railroads report they have seen no indications of a systemic problem involving electrode pitting, and that

railroads and welding companies have procedures in place to prevent electrode pitting and remediate it when it does occur. Accordingly, AAR asserted that FRA should not issue any recommendations burdening the industry such as those included in the draft safety advisory.

After consideration of AAR's comments and input from RSAC discussions, FRA agrees with AAR's position that, although stray arcing during the pressure electric welding process can result in the formation of electrode burns or pits on the web, head, or base of rail, and that fatigue cracking can develop from those burns or pits, railroads and welding companies have procedures in place addressing the issue of electrode pitting. Accordingly, in issuing Safety Advisory 2018–01, FRA has not adopted the specific recommended actions listed in its draft safety advisory and instead intends Safety Advisory 2018–01 to merely remind railroads, contractors, and the rail welding industry to be diligent in complying with existing practices and procedures designed to prevent electrode-induced pitting in rail and to mitigate the pitting when it does occur.

Safety Advisory 2018–01

Pressure electric welding is the process of using a hydraulically-operated welding head that clamps around two opposing rail ends, pressing an electrode on each rail, then hydraulically pulling the rail ends together while arcing current through the electrodes into the rails, causing them to essentially melt together to form a continuous rail. Stray arcing during this process results in the formation of electrode burns or pits on the web, head, or base of the rail. Fractures in the rail may originate from the electrode pits because they behave as stress raisers (also referred to as stress concentrations). Fatigue cracks may develop at locations of stress concentration. Once a fatigue crack initiates, the localized stress encourages the growth of the crack, which may potentially lead to rail failure. FRA believes electrode pitting may be a contributing factor, if not the root cause, in some accidents involving rail web cracking.

Figure 1 below shows a photograph of a rail with electrode pits in the web. The location of these electrode pits, when they occur, is typically four to eight inches on either side of the weld. Electrode-induced pitting from pressure electric welding may also occur in the head and base of the rail. It is unclear whether traditional ultrasonic rail

testing can consistently detect electrode-induced pitting.

In 2016, FRA's Office of Railroad Safety requested technical support from The National Transportation Systems Center (Volpe) to study the fatigue and fracture behavior of rails with pitting from electrodes used in welding. Volpe enlisted technical support from the U.S. Army's Benét Laboratories (Benét) to conduct forensic examination of three rail sections with electrode-induced pitting in the web from the pressure electric welding process. FRA obtained these rails from members of the railroad industry. Benét's examination included fractography (the science of studying fracture surfaces to identify the origin and causes of fracture), metallography (the science of studying the microstructure of metals to provide information concerning the properties and processing history of metallic alloys), and testing to determine the chemical composition and tensile mechanical properties of the rail steel. Benét confirmed the electrode-induced web fatigue cracking is a result of pitting caused by inadequate electrode-to-rail contact.

Specifically, Benét's metallurgical analyses concluded the cracking in the rail web originated from the pitting created by inadequate electrode-to-rail contact during the pressure electric welding process. The fractographic and metallographic examinations revealed evidence of fatigue cracking originating from the pitting and fast fracture once the fatigue crack reached a critical length. Figure 2 below shows three photographs of the fracture surface of a crack found in one of the rails Benét examined. These photographs support the metallurgical evidence indicative of three stages of fatigue fracture: (1) Crack initiation or formation originating from the pitting; (2) crack propagation or growth by metal fatigue; and (3) final rupture or fast fracture. Figure 3 below shows photographs of the microstructure near the electrode pits in each examined rail, providing further evidence the cracking originated from the pitting created by improper electrode contact during welding.

The results from the metallurgical analysis also suggested premature and sudden rail failure may result from high wheel-impact load (e.g., flat wheel), especially in cold-weather environments when the longitudinal rail force is tensile. Results from the chemical analysis and mechanical testing indicated the chemistry and mechanical properties of the rails selected for evaluation were within specifications the American Railway Engineering and Maintenance-of-Way

Association (AREMA) published, except for the hardness measurements in one rail, which were slightly lower than the AREMA minimum. Hardness is a measure of the resistance of a material to surface indentation produced by a carbide indenter applied at a given load for a given length of time. The lower hardness in that rail, manufactured in the 1950s, may be attributed to lower concentrations (compared to the other two rails) of alloying elements, specifically carbon, silicon, and

chromium, which were still within AREMA tolerances. Testing of the chemistry and the mechanical properties revealed all three rails were made from standard quality steel containing no other defects except the electrode-induced pitting.

FRA recognizes that the industry already has practices and procedures in place to avoid electrode pitting during the pressure electric welding process. Therefore, FRA is issuing Safety Advisory 2018–01 to remind railroads,

railroad employees, railroad contractors, and welding companies and their employees of the importance of complying with those procedures to prevent electrode pitting and, ultimately, to prevent rail failures. (FRA has posted a copy of this notice on its public website, www.fra.dot.gov, where you may view the figures below in their full resolution.)

BILLING CODE 4910–06–P

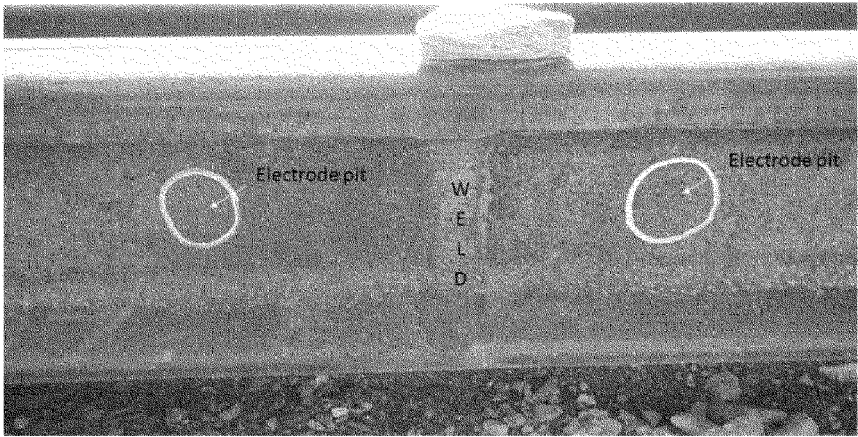


Figure 1: Electrode-Induced Pits in a Rail

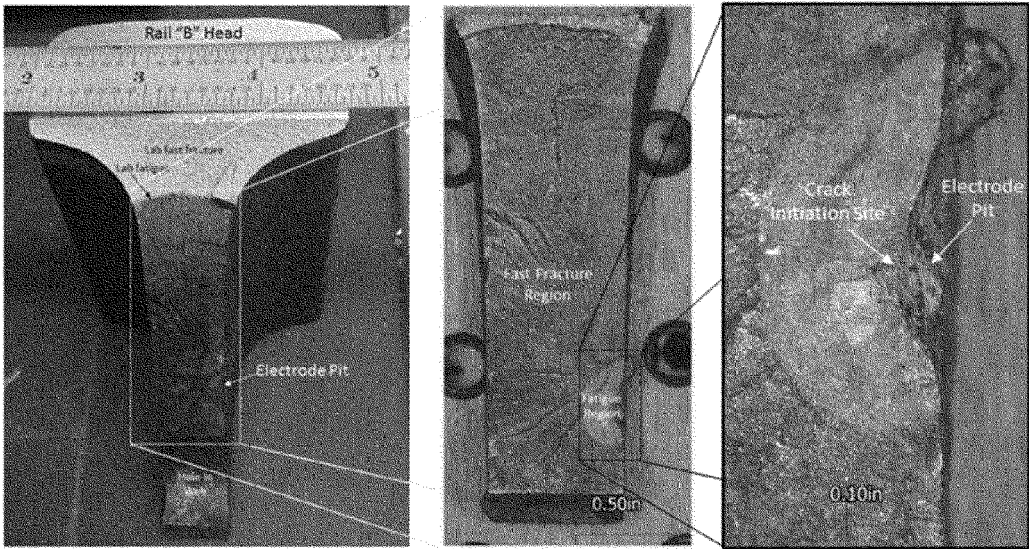


Figure 2: Photographs of Crack Fracture Surface in Examined Rail

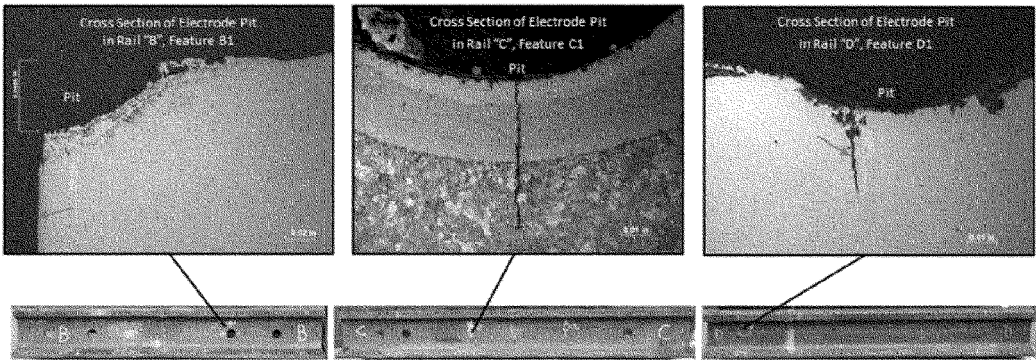


Figure 3: Photographs of Rail Cross Sections

Ronald Louis Batory,
Administrator.

[FR Doc. 2018-16022 Filed 7-26-18; 8:45 am]

BILLING CODE 4910-06-C

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

[Docket No. DOT-OST-2018-0108]

Vendor and Grantee Invoice Submission Process Change

AGENCY: U.S. Department of Transportation (DOT).

ACTION: Notice of enforced change with request for comments.

SUMMARY: The DOT invites the public and other Federal agencies to comment on a proposed vendor invoice submission change. DOT will submit the proposed information collection request to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. This notice sets forth new processes and procedures for vendors and grantees that submit invoices and receive payments for DOT Operating Administrations (OAs). Existing users of DOT's eInvoicing system, including grantees and vendors, will also be required to use *Login.gov*. DOT's objective is to improve efficiency and reduce unnecessary burden on vendors and grantees by eliminating existing manual processes for invoice entry, invoice approvals and user registration to reduce costs, increase timeliness of payments, and improve data quality. Introducing e-authentication to facilitate user validation and account management will greatly reduce the burden on vendors and grantees by eliminating the current paper based registration process. This electronic

invoicing process is currently used by DOT's grantee community and was successfully piloted to select vendors.

DATES: Comments must be submitted on or before September 24, 2018.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to the U.S. Department of Transportation, Office of Financial Management, B-30, Room W98-431, 1200 New Jersey Avenue SE, Washington DC 20590-0001, Anthony Chestnut, (202) 366-9661, DOTElectronicInvoicing@dot.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2105-0564.

Type of Request: Revision to previously approved information collection.

Background: This notice sets forth new processes and procedures for existing and future vendors and grantees that submit invoices and receive payments from DOT Operating Administrations (OAs). The vendors and grantees involved must meet the following requirements to participate:

- Vendors and grantees will need to have electronic internet access to register in GSA *Login.gov* and login into Delphi eInvoicing system.
- The identities of system users will be verified prior to receiving access to the Delphi eInvoicing system. Information required for *Login.gov* includes his/her email address, full name, phone number, and password.
- System users will Register with and Create an account with GSA *Login.gov*. System users will provide his/her email address and receive an email back to confirm. They will then create a password and input a telephone number and opt to receive either a personal call from *Login.gov* or text message with an authentication code.
- Once the system user is authenticated, he/she will complete a

System Access Request for Delphi eInvoicing system. The users will provide the following information: Full name, office phone number, work email address, vendor name, purchase order (contract or grant award) numbers, and agency doing business with. System users will provide the form to DOT to finalize the access.

- Once access is complete, vendors will submit invoices electronically and DOT OAs will process invoices electronically.

Affected Public: All Current and Future DOT Vendors and grantees.

Total Estimated Number of Respondents: Greater than 5,000.

Total Estimated Number of Responses: Greater than 5,000.

Estimated Total Annual Burden Hours: 500 (Initial Registration Only Calculated at 5 Minutes per).

Frequency of Collection: One Time.

Annual Estimated Total Annual Burden Costs: \$5,000.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3520, as amended.

Issued in Washington, DC, on July 24, 2018.

Jennifer Funk,

Acting, Deputy Chief Financial Officer, Department of Transportation.

[FR Doc. 2018-16089 Filed 7-26-18; 8:45 am]

BILLING CODE 4910-9X-P



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Book 2 of 2 Books

Pages 35703–36398

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, et al.

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, and 495

[CMS–1693–P]

RIN 0938–AT31

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

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

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the Medicare physician fee schedule (PFS) and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 10, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1693–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1693–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1693–P, Mail

Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT:

Jamie Hermansen, (410) 786–2064, for any physician payment issues not identified below.

Lindsey Baldwin, (410) 786–1694, and Emily Yoder, (410) 786–1804, for issues related to evaluation and management (E/M) payment, communication technology-based services and telehealth services.

Isadora Gil, (410) 786–4532, for issues related to payment rates for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of a hospital, and work relative value units (RVUs).

Ann Marshall, (410) 786–3059, for issues related to E/M documentation guidelines.

Geri Mondowney, (410) 786–1172, or Donta Henson, (410) 786–1947, for issues related to geographic price cost indices (GPCIs).

Geri Mondowney, (410) 786–1172, or Tourette Jackson, (410) 786–4735, for issues related to malpractice RVUs.

Patrick Sartini, (410) 786–9252, for issues related to radiologist assistants.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, impacts, and conversion factor.

Pamela West, (410) 786–2302, for issues related to therapy services.

Edmund Kasaitis, (410) 786–0477, for issues related to reduction of wholesale acquisition cost (WAC)-based payment.

Sarah Harding, (410) 786–4001, or Craig Dobyski, (410) 786–4584, for issues related to aggregate reporting of applicable information for clinical laboratory fee schedule.

Amy Gruber, (410) 786–1542, or Glenn McGuirk, (410) 786–5723, for issues related to the ambulance fee schedule.

Corinne Axelrod, (410) 786–5620, for issues related to care management services and communication technology-based services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).

JoAnna Baldwin, (410) 786–7205, or Sarah Fulton, (410) 786–2749, for issues related to appropriate use criteria for advanced diagnostic imaging services.

David Koppel, (214) 767–4403, for issues related to Medicaid Promoting Interoperability Program.

Fiona Larbi, (410) 786–7224, for issues related to the Medicare Shared Savings Program Quality Measures.

Matthew Edgar, (410) 786–0698, for issues related to the physician self-referral law.

Molly MacHarris, (410) 786–4461, for inquiries related to Merit-based Incentive Payment System (MIPS).

Benjamin Chin, (410) 786–0679, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

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VI. Response to Comments

VII. Regulatory Impact Analysis Regulations Text

Appendix 1: Proposed MIPS Quality Measures

Appendix 2: Improvement Activities

Addenda Available Only Through the Internet on the CMS Website

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee->

for-Service-Payment/Physician FeeSched/PFS-Federal-Regulation-Notices.html. Click on the link on the left side of the screen titled, “PFS Federal Regulations Notices” for a chronological list of PFS **Federal Register** and other related documents. For the CY 2019 PFS Proposed Rule, refer to item CMS–1693–P. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact Jamie Hermansen at (410) 786–2064.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2017 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major proposed rule proposes to revise payment policies under the Medicare PFS and make other policy changes, including proposals to implement certain provisions of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted on February 9, 2018), related to Medicare Part B payment, applicable to services furnished in CY 2019. In addition, this proposed rule includes proposals related to payment policy changes that are addressed in section III. of this proposed rule. We are requesting public comments on all of the proposals being made in this proposed rule.

1. Summary of the Major Provisions

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: Work; practice expense (PE); and malpractice (MP) expense. In addition, the statute requires that we establish by regulation each year’s payment amounts for all physicians’ services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major proposed rule, we are proposing to establish RVUs

for CY 2019 for the PFS, and other Medicare Part B payment policies, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule includes discussions and proposals regarding:

- Potentially Misvalued Codes.
- Communication Technology-Based Services.
- Valuation of New, Revised, and Misvalued Codes.
- Payment Rates under the PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital.

Provisions in the Bipartisan Budget Act of 2018.

- Appropriate Use Criteria for Advanced Diagnostic Imaging Services.
- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs).
- Medicare Shared Savings Program Quality Measures.
- Physician Self-Referral Law.
- CY 2019 Updates to the Quality Payment Program.
- Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers.
- Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information.

2. Summary of Costs and Benefits

We have determined that this major proposed rule is economically significant. For a detailed discussion of the economic impacts, see section VII. of this proposed rule.

II. Provisions of the Proposed Rule for the PFS

A. Background

Since January 1, 1992, Medicare has paid for physicians’ services under section 1848 of the Act, “Payment for Physicians’ Services.” The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into

payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989) (OBRA ’89), and the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) (OBRA ’90). The final rule published on November 25, 1991 (56 FR 59502) set forth the first fee schedule used for payment for physicians’ services.

We note that throughout this major proposed rule, unless otherwise noted, the term “practitioner” is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

1. Development of the Relative Values

a. Work RVUs

The work RVUs established for the initial fee schedule, which was implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians’ services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other

public commenters, and the rationale for their recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, enacted on October 31, 1994), amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding MP expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in the November 2, 1998 final rule (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: The Clinical Practice Expert Panel (CPEP) data; and the AMA's Socioeconomic Monitoring System (SMS) data. These data sources are described in greater detail in the CY 2012 PFS final rule with comment period (76 FR 73033).

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference,

if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those facility resources is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' MP insurance premium data from all the states, the District of Columbia, and

Puerto Rico. For more information on MP RVUs, see section II.C. of this proposed rule.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed 5-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the 5-year reviews, beginning for CY 2009, CMS and the RUC identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, that require the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VII. of this proposed rule, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than \$20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than \$20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each

component. Please refer to the CY 2017 PFS final rule with comment period for a discussion of the last GPCI update (81 FR 80261 through 80270).

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The formula for calculating the Medicare PFS payment amount for a given service and fee schedule area can be expressed as:

$$\text{Payment} = [(\text{RVU work} \times \text{GPCI work}) + (\text{RVU PE} \times \text{GPCI PE}) + (\text{RVU MP} \times \text{GPCI MP})] \times \text{CF}$$

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia CF, in a manner to ensure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate CF for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

B. Determination of Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding MP expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physician's service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in

furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units under the PFS and Proposed Changes to the Practice Expense Methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the

magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file called "CY 2019 PFS Proposed Rule PE/HR" on the CMS website under downloads for the CY

2019 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

For CY 2019, we have incorporated the available utilization data for two new specialties, each of which became a recognized Medicare specialty during 2017. These specialties are Hospitalists and Advanced Heart Failure and Transplant Cardiology. We are proposing to use proxy PE/HR values for these new specialties, as there are no PPIS data for these specialties, by crosswalking the PE/HR as follows from specialties that furnish similar services in the Medicare claims data:

- Hospitalists from Emergency Medicine.
- Advanced Heart Failure and Transplant Cardiology from Cardiology.

The proposal is reflected in the “CY 2019 PFS Proposed Rule PE/HR” file available on the CMS website under the supporting data files for the CY 2019 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of \$400 from our PE database and another service has a direct cost sum of \$200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion (see section II.B.2.b of this proposed rule). The general approach to developing the

indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).

- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.

- Next, we incorporated the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we

establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: A professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file called “Calculation of PE RVUs under Methodology for Selected Codes” which is available on our website under downloads for the CY 2019 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>. This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.
Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the proposed aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to a RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a proposal in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we instead use the expected specialty that we identify on a list developed based on medical review and input from expert stakeholders. We display this list of expected specialty assignments as part

of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, “always therapy” services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 59283) a proposal to apply these service-level overrides for both PE and MP, rather than one or the other category.

For CY 2019, we are proposing to add 28 additional codes that we have identified as low volume services to the list of codes for which we assign the expected specialty. Based on our own medical review and input from the RUC and from specialty societies, we are proposing to assign the expected specialty for each code as indicated in Table 1. For each of these codes, only the professional component (reported with the –26 modifier) is nationally priced. The global and technical components are priced by the Medicare Administrative Contractors (MACs) which establish RVUs and payment amounts for these services. The list of codes that we are proposing to add is displayed in Table 1.

TABLE 1—NEW ADDITIONS TO EXPECTED SPECIALTY LIST FOR LOW VOLUME SERVICES

CPT code	Mod	Short descriptor	Expected specialty	2017 Utilization
70557	26	Mri brain w/o dye	Diagnostic Radiology	126
70558	26	Mri brain w/dye	Diagnostic Radiology	32
74235	26	Remove esophagus obstruction	Gastroenterology	10
74301	26	X-rays at surgery add-on	Diagnostic Radiology	73
74355	26	X-ray guide intestinal tube	Diagnostic Radiology	11
74445	26	X-ray exam of penis	Urology	26
74742	26	X-ray fallopian tube	Diagnostic Radiology	5
74775	26	X-ray exam of perineum	Diagnostic Radiology	80
75801	26	Lymph vessel x-ray arm/leg	Diagnostic Radiology	114
75803	26	Lymph vessel x-ray arms/leg	Diagnostic Radiology	41
75805	26	Lymph vessel x-ray trunk	Diagnostic Radiology	50
75810	26	Vein x-ray spleen/liver	Diagnostic Radiology	46
76941	26	Echo guide for transfusion	Obstetrics/Gynecology	15
76945	26	Echo guide villus sampling	Obstetrics/Gynecology	31
76975	26	Gi endoscopic ultrasound	Gastroenterology	49
78282	26	Gi protein loss exam	Diagnostic Radiology	8
79300	26	Nuclr rx interstit colloid	Diagnostic Radiology	2
86327	26	Immunoelectrophoresis assay	Pathology	24
87164	26	Dark field examination	Pathology	30
88371	26	Protein western blot tissue	Pathology	2
93532	26	R & I heart cath congenital	Cardiology	28
93533	26	R & I heart cath congenital	Cardiology	36
93561	26	Cardiac output measurement	Cardiology	28
93562	26	Card output measure subsq	Cardiology	38
93616	26	Esophageal recording	Cardiology	38
93624	26	Electrophysiologic study	Cardiology	51
95966	26	Meg evoked single	Neurology	72
95967	26	Meg evoked each addl	Neurology	61

The complete list of expected specialty assignments for individual low volume services, including the proposed assignments for the codes identified in Table 1, is available on our website under downloads for the CY 2019 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.

- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(Note: For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file called “Calculation of PE RVUs under Methodology for Selected Codes”, the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from

Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the proposed aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS budget neutrality. (See “Specialties excluded from ratesetting calculation” later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- **Specialties excluded from ratesetting calculation:** For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 2.

TABLE 2—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Medical supply company with registered pharmacist.
59	Ambulance service supplier, <i>e.g.</i> , private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (<i>e.g.</i> , drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
B2	Pedorthic personnel.
B3	Medical supply company with pedorthic personnel.

• *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

• *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

• *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the

professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000

(Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

• *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any

service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 3 details the manner in which the modifiers are applied.

TABLE 3—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

Modifier	Description	Volume adjustment	Time adjustment
80, 81, 82	Assistant at Surgery	16%	Intraoperative portion.
AS	Assistant at Surgery—Physician Assistant.	14% (85% * 16%)	Intraoperative portion.
50 or LT and RT	Bilateral Surgery	150%	150% of work time.
51	Multiple Procedure	50%	Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.

TABLE 3—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES—Continued

Modifier	Description	Volume adjustment	Time adjustment
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- *Work RVUs:* The setup file contains the work RVUs from this proposed rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

$$(1/(\text{minutes per year} * \text{usage})) * \text{price} * ((\text{interest rate}/(1 - (1/((1 + \text{interest rate})^{\text{life of equipment}})))) + \text{maintenance})$$

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.

usage = variable, see discussion in this proposed rule.

price = price of the particular piece of equipment.

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

interest rate = variable, see discussion in this proposed rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Stakeholders have often suggested that particular equipment items are used less frequently than 50 percent of the time in the typical setting and that CMS should reduce the equipment utilization rate based on these recommendations. We appreciate and share stakeholders' interest in using the most accurate assumption regarding the equipment utilization rate for particular equipment items. However, we believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate within the relative value system. We welcome the submission of data that illustrates an alternative rate.

Maintenance: This factor for maintenance was finalized in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We do not believe that voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining maintenance factor, we do not believe that we have sufficient information at present to propose a variable maintenance factor for equipment cost per minute pricing. We continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

Interest Rate: In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small

Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). We are not proposing any changes to these interest rates for CY 2019. The interest rates are listed in Table 4.

TABLE 4—SBA MAXIMUM INTEREST RATES

Price	Useful life	Interest rate (%)
<\$25K	<7 Years	7.50
\$25K to \$50K	<7 Years	6.50
>\$50K	<7 Years	5.50
<\$25K	7+ Years	8.00
\$25K to \$50K	7+ Years	7.00
>\$50K	7+ Years	6.00

3. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2019 direct PE input database, which is available on the CMS website under downloads for the CY 2019 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640–67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and postservice periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of

equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for “Availability of prior images confirmed”, 2 minutes for “Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocol by radiologist”, 2 minutes for “Review examination with interpreting MD”, and 1 minute for “Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.” In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a proposal to establish a range of appropriate standard minutes for the clinical labor activity, “Technologist QC images in PACS, checking for all images, reformats, and dose page.” These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a proposal to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values.

We also finalized standard times for clinical labor tasks associated with

pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902) at 4 minutes for “Accession specimen/prepare for examination”, 0.5 minutes for “Assemble and deliver slides with paperwork to pathologists”, 0.5 minutes for “Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation”, 1 minute for “Clean room/equipment following procedure”, 1 minute for “Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste”, and 1 minute for “Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable).” We do not believe these activities would be dependent on number of blocks or batch size, and we believe that these values accurately reflect the typical time it takes to perform these clinical labor tasks.

Historically, the RUC has submitted a “PE worksheet” that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC’s development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC’s use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did for CY 2018, to facilitate rulemaking for CY 2019, we are continuing to display two versions of the Labor Task Detail public use file: One version with the old listing of clinical labor tasks, and one with the same tasks cross-walked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2019 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the “Prepare room, equipment and supplies” (CA013) clinical labor activity were split into 2 minutes for the “Prepare room, equipment and

supplies” activity and 1 minute for the “Confirm order, protocol exam” (CA014) activity. These RUC-reviewed codes do not currently have clinical labor time assigned for the “Confirm order, protocol exam” clinical labor task, and we do not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets.

As a result, we are proposing to maintain the 3 minutes of clinical labor time for the “Prepare room, equipment and supplies” activity and remove the clinical labor time for the “Confirm order, protocol exam” activity wherever we observed this pattern in the RUC-recommended direct PE inputs. If we had received RUC recommendations for codes that currently include clinical labor time for the “Confirm order, protocol exam” clinical labor task, we would have left the recommended clinical labor times unchanged, but there were no such codes reviewed for CY 2019. We note that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being used in the calculation of PE RVUs.

b. Equipment Recommendations for Scope Systems

During our routine reviews of direct PE input recommendations, we have regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. Some of the scopes include video systems bundled into the equipment item, some of them include scope accessories as part of their price, and some of them are standalone scopes with no other equipment included. It is not always clear which equipment items related to scopes fall into which of these categories. We have also frequently found anomalies in the equipment recommendations, with equipment items that consist of a scope and video system bundle recommended, along with a separate scope video system. Based on our review, the variations do not appear to be consistent with the different code descriptions.

To promote appropriate relativity among the services and facilitate the transparency of our review process, during the review of the recommended direct PE inputs for the CY 2017 PFS proposed rule, we developed a structure that separates the scope, the associated video system, and any scope accessories that might be typical as distinct equipment items for each code. Under this approach, we proposed standalone

prices for each scope, and separate prices for the video systems and accessories that are used with scopes.

(1) Scope Equipment

Beginning in the CY 2017 proposed rule (81 FR 46176 through 46177), we proposed standardizing refinements to the way scopes have been defined in the direct PE input database. We believe that there are four general types of scopes: Non-video scopes; flexible scopes; semi-rigid scopes, and rigid scopes. Flexible scopes, semi-rigid scopes, and rigid scopes would typically be paired with one of the scope video systems, while the non-video scopes would not. The flexible scopes can be further divided into diagnostic (or non-channelled) and therapeutic (or channelled) scopes. We proposed to identify for each anatomical application: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channelled flexible video scope; and (5) a channelled flexible video scope. We proposed to classify the existing scopes in our direct PE database under this classification system, to improve the transparency of our review process and improve appropriate relativity among the services. We planned to propose input prices for these equipment items through future rulemaking.

We proposed these changes only for the reviewed codes for CY 2017 that made use of scopes, along with updated prices for the equipment items related to scopes utilized by these services. But, we did not propose to apply these policies to codes with inputs reviewed prior to CY 2017. We also solicited comment on this separate pricing structure for scopes, scope video systems, and scope accessories, which we could consider proposing to apply to other codes in future rulemaking. We did not finalize price increases for a series of other scopes and scope accessories, as the invoices submitted for these components indicated that they are different forms of equipment with different product IDs and different prices. We did not receive any data to indicate that the equipment on the newly submitted invoices was more typical in its use than the equipment that we were currently using for pricing.

We did not make further changes to existing scope equipment in CY 2017 to allow the RUC's PE Subcommittee the opportunity to provide feedback. However, we believed there was some miscommunication on this point, as the RUC's PE Subcommittee workgroup that was created to address scope systems stated that no further action was required following the finalization of our proposal. Therefore, we made

further proposals in CY 2018 (82 FR 33961 through 33962) to continue clarifying scope equipment inputs, and sought comments regarding the new set of scope proposals. We considered creating a single scope equipment code for each of the five categories detailed in this rule: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channelled flexible video scope; and (5) a channelled flexible video scope. Under the current classification system, there are many different scopes in each category depending on the medical specialty furnishing the service and the part of the body affected. We stated our belief that the variation between these scopes was not significant enough to warrant maintaining these distinctions, and we believed that creating and pricing a single scope equipment code for each category would help provide additional clarity. We sought public comment on the merits of this potential scope organization, as well as any pricing information regarding these five new scope categories.

After considering the comments on the CY 2018 proposed rule, we did not finalize our proposal to create and price a single scope equipment code for each of the five categories previously identified. Instead, we supported the recommendation from the commenters to create scope equipment codes on a per-specialty basis for six categories of scopes as applicable, including the addition of a new sixth category of multi-channelled flexible video scopes. Our goal is to create an administratively simple scheme that will be easier to maintain and help to reduce administrative burden. We look forward to receiving detailed recommendations from expert stakeholders regarding the scope equipment items that would be typically required for each scope category, as well as the proper pricing for each scope.

(2) Scope Video System

We proposed in the CY 2017 PFS proposed rule (81 FR 46176 through 46177) to define the scope video system as including: (1) A monitor; (2) a processor; (3) a form of digital capture; (4) a cart; and (5) a printer. We believe that these equipment components represent the typical case for a scope video system. Our model for this system was the "video system, endoscopy (processor, digital capture, monitor, printer, cart)" equipment item (ES031), which we proposed to re-price as part of this separate pricing approach. We obtained current pricing invoices for the endoscopy video system as part of our investigation of these issues involving

scopes, which we proposed to use for this re-pricing. In response to comments, we finalized the addition of a digital capture device to the endoscopy video system (ES031) in the CY 2017 PFS final rule (81 FR 80188). We finalized our proposal to price the system at \$33,391, based on component prices of \$9,000 for the processor, \$18,346 for the digital capture device, \$2,000 for the monitor, \$2,295 for the printer, and \$1,750 for the cart. In the CY 2018 PFS final rule (82 FR 52991 through 52993), we outlined, but did not finalize, a proposal to add an LED light source into the cost of the scope video system (ES031), which would remove the need for a separate light source in these procedures. We also described a proposal to increase the price of the scope video system by \$1,000 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.). With the addition of the LED light (equipment code EQ382 at a price of \$1,915), the updated total price of the scope video system would be set at \$36,306. We did not finalize this updated pricing to the scope video system in CY 2018, and indicated our intention to address these changes in CY 2019 to incorporate feedback from expert stakeholders.

(3) Scope Accessories

We understand that there may be other accessories associated with the use of scopes. We finalized a proposal in the CY 2017 PFS final rule (81 FR 80188) to separately price any scope accessories outside the use of the scope video system, and individually evaluate their inclusion or exclusion as direct PE inputs for particular codes as usual under our current policy based on whether they are typically used in furnishing the services described by the particular codes.

(4) Scope Proposals for CY 2019

We understand that the RUC has convened a Scope Equipment Reorganization Workgroup that will be incorporating feedback from expert stakeholders with the intention of making recommendations to us on scope organization and scope pricing. Since the workgroup was not convened in time to submit recommendations for the CY 2019 PFS rulemaking cycle, we are proposing to delay proposals for any further changes to scope equipment until CY 2020 so that we can incorporate the feedback from the aforementioned workgroup. However,

we are proposing to update the price of the scope video system (ES031) from its current price of \$33,391 to a price of \$36,306 to reflect the addition of the LED light and miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories, as we explained in detail in the CY 2018 PFS final rule (82 FR 52992 through 52993). We are also proposing to update the name of the ES031 equipment item from “video system, endoscopy (processor, digital capture, monitor, printer, cart)” to “scope video system (monitor, processor, digital capture, cart, printer, LED light)” to reflect the fact that the use of the ES031 scope video system is not limited to endoscopy procedures.

**c. Balloon Sinus Surgery Kit (SA106)
Comment Solicitation**

Several stakeholders contacted CMS with regard to the use of the kit, sinus surgery, balloon (maxillary, frontal, or sphenoid) (SA106) supply in CPT codes 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation)), transnasal or via canine fossa, 31296 (Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)), and 31297 (Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)). The stakeholders stated that the price of the SA106 supply (currently \$2,599.86) had decreased significantly since it was priced through rulemaking

for CY 2011 (75 FR 73351 through 75532), and that the Medicare payment for these three CPT codes using the supply no longer seemed to be in proportion to what the kits cost. They also indicated that the same catheter could be used to treat multiple sinuses rather than being a disposable one-time use supply. The stakeholders stated that marketing firms and sales representatives are advertising these CPT codes as a method for generating additional profits due to the payment for the procedures exceeding the resources typically needed to furnish the services, and requested that CMS investigate the use of the SA106 supply in these codes.

We appreciate the information supplied by the stakeholders regarding the use of the balloon sinus surgery kit. When CPT codes 31295–31297 were initially reviewed during the CY 2011 and CY 2012 PFS rulemaking cycles (75 FR 73251, and 76 FR 73184 through 73186, respectively), we expressed our reservations about the pricing and the typical quantity of this supply item used in furnishing these services. The RUC recommended for the CY 2012 rulemaking cycle that CMS remove the balloon sinus surgery kit from each of these codes and implement separately billable alpha-numeric HCPCS codes to allow practitioners to be paid the cost of the disposable kits per patient encounter instead of per CPT code. We stated at the time, and we continue to believe, that this option presents a series of potential problems that we have

addressed previously in the context of the broader challenges regarding our ability to price high cost disposable supply items. (For a discussion of this issue, we direct the reader to our discussion in the CY 2011 PFS final rule with comment period (75 FR 73251)). We stated at the time that since the balloon sinus surgery kits can be used when furnishing more than one service to the same beneficiary on the same day, we believed that it would be appropriate to include 0.5 balloon sinus surgery kits for each of the three codes, and we have maintained this 0.5 supply quantity when CPT codes 31295–31297 were recently reviewed again in CY 2018.

In light of the additional information supplied by the stakeholders, we are soliciting comments on two aspects of the use of the balloon sinus surgery kit (SA106) supply. First, we are soliciting comments on whether the 0.5 supply quantity of the balloon sinus surgery kit in CPT codes 31295–31297 would be typical for these procedures. We are concerned that the same kit can be used when furnishing more than one service to the same beneficiary on the same day, and that even the 0.5 supply quantity may be overstating the resources typically needed to furnish each service. Second, we are soliciting comments on the pricing of the balloon sinus surgery kit, given that we have received letters stating that the price has decreased since the initial pricing in the CY 2011 final rule. See Table 5 for the current component pricing of the balloon sinus surgery kit.

TABLE 5—BALLOON SINUS SURGERY KIT (SA106) PRICE

Supply components	Quantity	Unit	Price
kit, sinus surgery, balloon (maxillary, frontal, or sphenoid)	kit	\$2599.86
Sinus Guide Catheter	1	item	444.00
Sinus Balloon Catheter	1	item	820.80
Sinus Illumination System (100 cm lighted guidewire)	1	item	454.80
Light Guide Cable (8 ft)	1	item	514.80
ACMI/Stryker Adaptor	1	item	42.00
Sinus Guide Catheter Handle	1	item	66.00
Sinus Irrigation Catheter (22 cm)	1	item	150.00
Sinus Balloon Catheter Inflation Device	1	item	89.46
Extension Tubing (High Pressure) (20 in)	1	item	18.00

We are interested in any information regarding possible changes in the pricing for this kit or its individual components since the initial pricing we adopted in CY 2011.

**d. Technical Corrections to Direct PE
Input Database and Supporting Files**

Subsequent to the publication of the CY 2018 PFS final rule, stakeholders alerted us to several clerical inconsistencies in the direct PE

database. We are proposing to correct these inconsistencies as described in this proposed rule and reflected in the CY 2019 proposed direct PE input database displayed on the CMS website under downloads for the CY 2019 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

For CY 2019, we are proposing to address the following inconsistencies:

- The RUC alerted us that there are 165 CPT codes billed with an office E/M code more than 50 percent of the time in the nonfacility setting that have more minimum multi-specialty visit supply packs (SA048) than post-operative visits included in the code's global period. This indicates that either the inclusion of office E/M services was not accounted for in the code's global period when these codes were initially reviewed by the PE Subcommittee, or

that the PE Subcommittee initially approved a minimum multi-specialty visit supply pack for these codes without considering the resulting overlap of supplies between SA048 and the E/M supply pack (SA047). The RUC

regarded these overlapping supply packs as a duplication, due to the fact that the quantity of the SA048 supply exceeded the number of postoperative visits, and requested that CMS remove the appropriate number of supply item

SA048 from 165 codes. After reviewing the quantity of the SA048 supply pack included for the codes in question, we are proposing to refine the quantity of minimum multi-specialty visit packs as displayed in Table 6.

TABLE 6—PROPOSED REFINEMENTS—MINIMUM MULTISPECIALTY VISIT PACK (SA048)

CPT code	Number of post-op office visits	CY 2018 nonfacility quantity of minimum visit pack (SA048)	Proposed CY 2019 nonfacility quantity of minimum visit pack (SA048)
10040	1	2	1
10060	1	2	1
10061	2	3	2
10080	1	2	1
10120	1	2	1
10121	1	2	1
10180	1	2	1
11200	1	2	1
11300	0	1	0
11301	0	1	0
11302	0	1	0
11303	0	1	0
11306	0	1	0
11307	0	1	0
11310	0	1	0
11311	0	1	0
11312	0	1	0
11400	1	2	1
11750	1	2	1
11900	0	1	0
11901	0	1	0
12001	0	1	0
12002	0	1	0
12004	0	1	0
12011	0	1	0
12013	0	1	0
16020	0	1	0
17000	1	2	1
17004	1	2	1
17110	1	2	1
17111	1	2	1
17260	1	2	1
17270	1	2	1
17280	1	2	1
19100	0	1	0
20005	1	2	1
20520	1	2	1
21215	6	7	6
21550	1	2	1
21920	1	2	1
22310	1.5	2.5	1.5
23500	2.5	3.5	2.5
23570	2.5	3.5	2.5
23620	3	4	3
24500	4	5	4
24530	4	5	4
24650	3	4	3
24670	3	4	3
25530	3	4	3
25600	5	6	5
25605	5	6	5
25622	3.5	4.5	3.5
25630	3	4	3
26600	4	5	4
26720	2	3	2
26740	2.5	3.5	2.5
26750	2	3	2
27508	4	5	4
27520	3.5	4.5	3.5

TABLE 6—PROPOSED REFINEMENTS—MINIMUM MULTISPECIALTY VISIT PACK (SA048)—Continued

CPT code	Number of post-op office visits	CY 2018 nonfacility quantity of minimum visit pack (SA048)	Proposed CY 2019 nonfacility quantity of minimum visit pack (SA048)
27530	4	5	4
27613	1	2	1
27750	3.5	4.5	3.5
27760	4	5	4
27780	3.5	4.5	3.5
27786	3.5	4.5	3.5
27808	4	5	4
28190	1	2	1
28400	3	4	3
28450	2.5	3.5	2.5
28490	1.5	2.5	1.5
28510	1.5	2.5	1.5
30901	0	1	0
30903	0	1	0
30905	0	1	0
31000	1	2	1
31231	0	1	0
31233	0	1	0
31235	0	1	0
31238	0	1	0
31525	0	1	0
31622	0	1	0
32554	0	1	0
36600	0	1	0
38220	0	1	0
40490	0	1	0
42800	1	2	1
43200	0	1	0
45330	0	1	0
46040	3	4	3
46050	1	2	1
46083	1	2	1
46320	0.5	1.5	0.5
46600	0	1	0
46604	0	1	0
46900	1	2	1
51102	0	2	0
51701	0	1	0
51702	0	1	0
51703	0	1	0
51710	0	1	0
51725	0	1	0
51736	0	1	0
51741	0	1	0
51792	0	1	0
51798	0	1	0
52000	0	1	0
52001	0	1	0
52214	0	1	0
52265	0	1	0
52281	0	1	0
52285	0	1	0
53601	0	1	0
53621	0	1	0
53660	0	1	0
53661	0	1	0
54050	1	2	1
54056	1	2	1
54100	0	1	0
54235	0	1	0
54450	0	1	0
55000	0	1	0
56405	1	2	1
56605	0	1	0
56820	0	1	0
57061	1	2	1
57100	0	1	0

TABLE 6—PROPOSED REFINEMENTS—MINIMUM MULTISPECIALTY VISIT PACK (SA048)—Continued

CPT code	Number of post-op office visits	CY 2018 nonfacility quantity of minimum visit pack (SA048)	Proposed CY 2019 nonfacility quantity of minimum visit pack (SA048)
57420	0	1	0
57500	0	1	0
57505	1	2	1
62252	0	1	0
62367	0	1	0
62368	0	1	0
62370	0	1	0
64413	0	1	0
64420	0	1	0
64450	0	1	0
64611	1	2	1
69000	1	2	1
69100	0	1	0
69145	1.5	2.5	1.5
69210	0	1	0
69420	1	2	1
69433	1	2	1
69610	1	2	1
93292	0	1	0
93303	0	1	0
94667	0	1	0
95044	0	0.028	0
95870	0	1	0
95921	0	1	0
95922	0	1	0
95924	0	1	0
95972	0	1	1
96904	0	1	1

In general, we are proposing to align the number of minimum multi-specialty visit packs with the number of post-operative office visits included in these codes. We are not proposing any supply pack quantity refinements for CPT codes 11100, 95974, or 95978 since they are being deleted for CY 2019. We are also not proposing any supply pack quantity refinements for CPT codes 45300, 46500, 57150, 57160, 58100, 64405, 95970, or HCPCS code G0268 since these codes were reviewed by the RUC this year and their previous direct PE inputs will be superseded by the new direct PE inputs we establish through this rulemaking process for CY 2019.

- A stakeholder notified us regarding a potential rank order anomaly in the direct PE inputs established for the Shaving of Epidermal or Dermal Lesions code family through PFS rulemaking for CY 2013. Three of these CPT codes describe benign shave removal of increasing lesion sizes: CPT code 11310 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less), CPT code 11311 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter

0.6 to 1.0 cm), and CPT code 11312 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 1.1 to 2.0 cm). Each of these codes has a progressively higher work RVU corresponding to the increasing lesion diameter, and the recommended direct PE inputs also increase progressively from CPT codes 11310 to 11311 to 11312. However, the nonfacility PE RVU we established for CPT code 11311 is lower than the nonfacility PE RVU for CPT code 11310, which the stakeholder suggested may represent a rank order anomaly.

We reviewed the direct PE inputs for CPT code 11311 and found that there were clerical inconsistencies in the data entry that resulted in the assignment of the lower nonfacility PE RVU for CPT code 11311. We propose to revise the direct PE inputs to reflect the ones previously finalized through rulemaking for CPT code 11311.

- In CY 2018, we inadvertently assigned too many minutes of clinical labor time for the “Obtain vital signs” task to three therapy codes, given that these codes are typically billed in multiple units and in conjunction with other therapy codes for the same patient

on the same day, and we do not believe that it would be typical for clinical staff to obtain vital signs for each time a code is reported. The codes are: CPT code 97124 (Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)); CPT code 97750 (Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes); and CPT code 97755 (Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes).

Therefore, we are proposing to refine the “Obtain vital signs” clinical labor task for these three codes back to their previous times of 1 minute for CPT codes 97124 and 97750 and to 3 minutes for CPT code 97755. We are also proposing to refine the equipment time for the table, mat, hi-lo, 6 x 8 platform (EF028) for CPT code 97124 to reflect the change in the clinical labor time.

- We received a letter from a stakeholder alerting us to an anomaly in

the direct PE inputs for CPT code 52000 (Cystourethroscopy (separate procedure)). The stakeholder stated that the inclusion of an endoscope disinfectant, rigid or fiberoptic, w-cart equipment item (ES005) was inadvertently overlooked in the recommendations for CPT code 52000 when it was reviewed during PFS rulemaking for CY 2017, and that the equipment would be necessary for endoscope sterilization. The stakeholder requested that this essential piece of equipment should be added to the direct PE inputs for CPT code 52000.

After reviewing the direct PE inputs for this code, we agree with the stakeholder and we are proposing to add the endoscope disinfectant (ES005) to CPT code 52000, and to add 22 minutes of equipment time for that item to match the equipment time of the other non-scope items included in this code.

e. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. For CY 2019, we are proposing the following price updates for existing direct PE inputs.

We are proposing to update the price of four supplies and one equipment item in response to the public submission of invoices. As these pricing updates were each part of the formal review for a code family, we are proposing that the new pricing take effect for CY 2019 for these items instead of being phased in over 4 years. For the details of these proposed price updates, please refer to section II.H of this proposed rule Table 16: Invoices Received for Existing Direct PE Inputs.

(1) Market-Based Supply and Equipment Pricing Update

Section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that

would improve the valuation of services under the PFS.

As part of our authority under section 1848(c)(2)(M) of the Act, as added by the PAMA, we initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for CY 2019. These supply and equipment prices were last systematically developed in 2004–2005. StrategyGen has submitted a report with updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. This report is available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

The StrategyGen team of researchers, attorneys, physicians, and health policy experts conducted a market research study of the supply and equipment items currently used in the PFS direct PE input database. Resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis to estimate and validate current prices for medical equipment and medical supplies. StrategyGen conducted secondary market research on each of the 2,072 DPEI medical equipment and supply items that CMS identified from the current DPEI. The primary and secondary resources StrategyGen used to gather price data and other information were:

- Telephone surveys with vendors for top priority items (Vendor Survey).
- Physician panel validation of market research results, prioritized by total spending (Physician Panel).
- The General Services Administration system (GSA).
- An aggregate health system buyers database with discounted prices (Buyers).
- Publicly available vendor resources, that is, Amazon Business, Cardinal Health (Vendors).
- **Federal Register**, current DPEI data, historical proposed and final rules prior to FY 2018, and other resources; that is, AMA RUC reports (References).

StrategyGen prioritized the equipment and supply research based on current share of PE RVUs attributable by item provided by CMS. StrategyGen developed the preliminary Recommended Price (RP) methodology based on the following rules in

hierarchical order considering both data representativeness and reliability:

1. If the market share, as well as the sample size, for the top three commercial products were available, the weighted average price (weighted by percent market share) was the reported RP. Commercial price, as a weighted average of market share, represents a more robust estimate for each piece of equipment and a more precise reference for the RP.

2. If StrategyGen did not have market share for commercial products, then they used a weighted average (weighted by sample size) of the commercial price and GSA price for the RP. The impact of the GSA price may be nominal in some of these cases since it is proportionate to the commercial samples sizes.

3. Otherwise, if single price points existed from alternate supplier sites, the RP was the weighted average of the commercial price and the GSA price.

4. Finally, if no data were available for commercial products, the GSA average price was used as the RP; and when StrategyGen could find no market research for a particular piece of equipment or supply item, the current CMS prices were used as the RP.

StrategyGen found that despite technological advancements, the average commercial price for medical equipment and supplies has remained relatively consistent with the current CMS price. Specifically, preliminary data indicate that there was no statistically significant difference between the estimated commercial prices and the current CMS prices for both equipment and supplies. This cumulative stable pricing for medical equipment and supplies appears similar to the pricing impacts of non-medical technology advancements where some historically high-priced equipment (that is, desktop PCs) has been increasingly substituted with current technology (that is, laptops and tablets) at similar or lower price points. However, while there were no statistically significant differences in pricing at the aggregate level, medical specialties will experience increases or decreases in their Medicare payments if CMS were to adopt the pricing updates recommended by StrategyGen. At the service level, there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing, although we note that codes with a sizable PE RVU decrease would be limited by the requirement to phase in significant reductions in RVUs, as required by section 1848(c)(7) of the Act. The phase-in requirement limits the maximum

RVU reduction for codes that are not new or revised to 19 percent in any individual calendar year.

After reviewing the StrategyGen report, we are proposing to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen. We believe that it is important to make use of the most current information available for supply and equipment pricing instead of continuing to rely on pricing information that is more than a decade old. Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, we are proposing to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY

2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. This approach is consistent with how we have previously incorporated significant new data into the calculation of PE RVUs, such as the 4-year transition period finalized in CY 2007 PFS final rule with comment period when changing to the “bottom-up” PE methodology (71 FR 69641). This transition period will not only ease the shift to the updated supply and equipment pricing, but will also allow interested parties an opportunity to review and respond to the new pricing information associated with their services.

We are proposing to implement this phase-in over 4 years so that supply and

equipment values transition smoothly from the prices we currently include to the final updated prices in CY 2022. We are proposing to implement this pricing transition such that one quarter of the difference between the current price and the fully phased in price is implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the proposed transition from the current to the fully-implemented new pricing is provided in Table 7.

TABLE 7—EXAMPLE OF DIRECT PE PRICING TRANSITION

Current Price	\$100	
Final Price	200	
Year 1 (CY 2019) Price	125	¼ difference between \$100 and \$200.
Year 2 (CY 2020) Price	150	⅓ difference between \$125 and \$200.
Year 3 (CY 2021) Price	175	½ difference between \$150 and \$200.
Final (CY 2022) Price	200	

For new supply and equipment codes for which we establish prices during the transition years (CYs 2019, 2020 and 2021) based on the public submission of invoices, we are proposing to fully implement those prices with no transition since there are no current prices for these supply and equipment items. These new supply and equipment codes would immediately be priced at their newly established values. We are also proposing that, for existing supply and equipment codes, when we establish prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family, they will be fully implemented for the year they are adopted without being phased in over the 4-year pricing transition. The formal review process for a HCPCS code includes a review of pricing of the supplies and equipment included in the code. When we find that the price on the submitted invoice is typical for the item in question, we believe it would be appropriate to finalize the new pricing immediately along with any other revisions we adopt for the code valuation.

For existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which we establish prices based on invoices submitted by the public, we are proposing to implement the established invoice price as the updated price and to phase in the new price over the

remaining years of the proposed 4-year pricing transition. During the proposed transition period, where price changes for supplies and equipment are adopted without a formal review of the HCPCS codes that include them (as is the case for the many updated prices we are proposing to phase in over the 4-year transition period), we believe it is important to include them in the remaining transition toward the updated price. We are also proposing to phase in any updated pricing we establish during 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family. We would implement the new prices for any such supplies and equipment over the remaining years of the proposed 4-year transition period. Our proposal is intended to minimize any potential disruptive effects during the proposed transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply and equipment items (meaning that these items are included in 100 or more codes).

We believe that implementing the proposed updated prices with a 4-year phase-in will improve payment accuracy, while maintaining stability and allowing stakeholders the

opportunity to address potential concerns about changes in payment for particular items. Updating the pricing of direct PE inputs for supplies and equipment over a longer time frame will allow more opportunities for public comment and submission of additional, applicable data. We welcome feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration. We are particularly interested in comments regarding the supply and equipment pricing for CPT codes 95165 and 95004 that are frequently used by the Allergy/Immunology specialty. The Allergy/Immunology specialty was disproportionately affected by the updated pricing, even with a 4-year phase-in. The direct PE costs for CPT code 95165 would go down from \$8.43 to \$8.17 as a result of the updated supply and equipment pricing information. This would result in the PE RVU for CPT code 96165 to decrease from 0.30 to 0.26. We are seeking feedback on the supply and equipment pricing for the affected codes typically performed by this specialty and whether the direct PE inputs should be reviewed along with the pricing. The full report from the contractor, including the updated supply and equipment pricing as it is proposed to be implemented over the proposed 4-year transition period, will be made available as a public use file displayed on the CMS website

under downloads for the CY 2019 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

To maintain relativity between the clinical labor, supplies, and equipment portions of the PE methodology, we believe that the rates for the clinical labor staff should also be updated along with the updated pricing for supplies and equipment. We seek public comment regarding whether to update the clinical labor wages used in developing PE RVUs in future calendar years during the 4-year pricing transition for supplies and equipment, or whether it would be more appropriate to update the clinical labor wages at a later date following the conclusion of the transition for supplies and equipment, for example, to avoid other potentially large shifts in PE RVUs during the 4-year pricing transition period.

(2) Breast Biopsy Software (EQ370)

Following the publication of the CY 2018 PFS final rule, a stakeholder contacted us and requested that we update the price for the Breast Biopsy software (EQ370) equipment. This equipment item currently lacks a price in the direct PE database, and when an invoice for the Breast Biopsy software was first submitted during the CY 2014 PFS rule, we stated that this item served clinical functions similar to other items already included in the Magnetic Resonance (MR) room equipment package (EL008) included in the same CPT codes under review. Therefore, we did not create new direct PE inputs for this equipment item (78 FR 74344 through 74345). The stakeholder suggested that this software is used to subtract the imaging raw data series from the MRI Scanner, reformat the images in multiple planes to allow accurate targeting of the lesion to be biopsied, identify the location of a fiducial marker on the patient's skin, and then target the location of the enhancing lesion to be biopsied. The stakeholder requested that EQ370 be renamed as "Breast MRI computer aided detection and biopsy guidance software" and added to existing CPT codes 19085 (Biopsy, breast, with placement of breast localization device(s) (e.g., clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance), 19086 (Biopsy, breast, with placement of breast localization device(s) (e.g., clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed,

percutaneous; each additional lesion, including magnetic resonance guidance), 19287 (Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance), and 19288 (Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance), as well as adding the equipment to two newly created MR breast codes with CAD, CPT codes 77X51 (Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD-real time lesion detection, characterization and pharmacokinetic analysis) when performed; unilateral) and 77X52 (Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD-real time lesion detection, characterization and pharmacokinetic analysis) when performed; bilateral). The stakeholder supplied an invoice with a purchase price of \$52,275 for the equipment.

After reviewing the use of the Breast Biopsy software (EQ370) equipment in these six codes, we are not proposing to update the price or add the software to these procedures. As we stated in the CY 2014 PFS final rule with comment period (78 FR 74345), we continue to believe that equipment item EQ370 serves clinical functions similar to other items already included in the MR room equipment package (EL008), and that it would be duplicative to include this Breast Biopsy software as a separate direct PE input. We also note that the RUC recommendations for the new CPT codes 77X51 and 77X52 do not include EQ370 in the recommended equipment for these procedures, and we do not have any reason to believe that the inclusion of additional Breast Biopsy software beyond what is already contained in the MR room equipment package would be typical. However, we will update the name of the EQ370 equipment item from "Breast Biopsy software" to the requested "Breast MRI computer aided detection and biopsy guidance software" to help better describe the equipment in question.

(3) Invoice Submission

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. For

CY 2019, we note that some stakeholders have submitted invoices for new, revised, or potentially misvalued codes after the February 10th deadline established for code valuation recommendations. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we would consider invoices submitted as public comments during the comment period following the publication of this proposed rule, and would consider any invoices received after February 10 or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices.

4. Adjustment to Allocation of Indirect PE for Some Office-Based Services

In the CY 2018 PFS final rule (82 FR 52999 through 53000), we established criteria for identifying the services most affected by the indirect PE allocation anomaly that does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings. We also finalized a modification in the PE methodology for allocating indirect PE RVUS to better reflect the relative indirect PE resources involved in furnishing these services. The methodology, as described, is based on the difference between the ratio of indirect PE to work RVUs for each of the codes meeting eligibility criteria and the ratio of indirect PE to work RVU for the most commonly reported visit code. We refer readers to the CY 2018 PFS final rule (82 FR 52999 through 53000) for a discussion of our process for selecting services subject to the revised methodology, as well as a description of the methodology, which we began implementing for CY 2018 as the first year of a 4-year transition. For CY 2019, we are proposing to continue with the second year of the transition of this adjustment to the standard process for allocating indirect PE.

C. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that the payment amount for each service paid under the PFS be composed of three components: Work; PE; and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource-based. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015

PFS final rule with comment period, we implemented the third review and update of MP RVUs. For a comprehensive discussion of the third review and update of MP RVUs see the CY 2015 proposed rule (79 FR 40349 through 40355) and final rule with comment period (79 FR 67591 through 67596).

To determine MP RVUs for individual PFS services, our MP methodology is composed of three factors: (1) Specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners; (2) service level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and (3) an intensity/complexity of service adjustment to the service level risk factor based on either the higher of the work RVU or clinical labor RVU. Prior to CY 2016, MP RVUs were only updated once every 5 years, except in the case of new and revised codes.

In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we finalized a policy to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk, intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the 3 most recent years of data instead of a single year of data. Under this approach, for new and revised codes, we generally assign a specialty risk factor to individual codes based on the same utilization assumptions we make regarding the specialty mix we use for calculating PE RVUs and for PFS budget neutrality. We continue to use the work RVU or clinical labor RVU to adjust the MP RVU for each code for intensity and complexity. In finalizing this policy, we stated that the specialty-specific risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews.

In CY 2017, we finalized the 8th GPCI update, which reflected updated MP premium data. We did not propose to use the updated MP premium data to propose updates for CY 2017 to the specialty risk factors used in the calculation of MP RVUs because it was inconsistent with the policy we previously finalized in the CY 2016 PFS final rule with comment period. That is, we indicated that the specialty-specific risk factors would continue to be

updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews. However, we solicited comment on whether we should consider doing so, perhaps as early as for CY 2018, prior to the fourth review and update of MP RVUs that must occur no later than CY 2020. After consideration of the comments received, we stated in the CY 2017 PFS final rule that we would consider the possibility of using the updated MP data to update the specialty risk factors used in the calculation of the MP RVUs prior to the next 5-year update in future rulemaking (81 FR 80191 through 80192).

In the CY 2018 PFS proposed rule, we proposed to use the updated MP data to update the specialty risk factors used in calculation of the MP RVUs prior to the next 5-year update (CY 2020). However, in the CY 2018 PFS final rule (82 FR 53000 through 53006), after consideration of the comments received and some differences we observed in the descriptions on the raw rate filings as compared to how those data were categorized to conform with the CMS specialties, we did not finalize our proposal to use the updated MP data. We are required to review, and if necessary, adjust the MP RVUs by CY 2020. We appreciate the feedback provided by commenters in response to the CY 2018 PFS proposed rule, and we are seeking additional comment regarding the next MP RVU update which must occur by CY 2020. Specifically, we are seeking comment on how we might improve the way that specialties in the state-level raw rate filings data are crosswalked for categorization into CMS specialty codes which are used to develop the specialty-level risk factors and the MP RVUs.

D. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

The health care community uses the term “telehealth” broadly to refer to medical services furnished via communication technology. Under current PFS payment rules, Medicare routinely pays for many of these kinds of services. This includes some kinds of remote patient monitoring (either as separate services or as parts of bundled services), interpretations of diagnostic tests when furnished remotely, and, under conditions specified in section 1834(m) of the Act, services that would otherwise be furnished in person but are instead furnished via real-time, interactive communication technology. Over the past several years, CMS has

also established several PFS policies to explicitly pay for non-face-to-face services included as part of ongoing care management.

While all of the kinds of services stated above might be called “telehealth” by patients, other payers and health care providers, we have generally used the term “Medicare telehealth services” to refer to the subset of services defined in section 1834(m) of the Act. Section 1834(m) of the Act defines Medicare telehealth services and specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. Section 1834(m)(4)(F)(i) of the Act enumerates certain Medicare telehealth services and section 1834(m)(4)(F)(ii) of the Act allows the Secretary to specify additional Medicare telehealth services using an annual process to add or delete services from the Medicare telehealth list. Section 1834(m)(4)(C) of the Act limits the scope of Medicare telehealth services for which payment may be made to those furnished to a beneficiary who is located in certain types of originating sites in certain, mostly rural, areas. Section 1834(m)(1) of the Act permits only physicians and certain other types of practitioners to furnish and be paid for Medicare telehealth services. Although section 1834(m)(4)(F)(ii) of the Act grants the Secretary the authority to add services to, and delete services from, the list of telehealth services based on the established annual process, it does not provide any authority to change the limitations relating to geography, patient setting, or type of furnishing practitioner because these requirements are specified in statute. However, we note that sections 50302, 50324, and 50325 of the Bipartisan Budget Act of 2018 (BBA 18) have modified or removed the limitations relating to geography and patient setting for certain telehealth services, including for certain home dialysis end-stage renal disease-related services, services furnished by practitioners in certain Accountable Care Organizations, and acute stroke-related services, respectively.

In the CY 2018 PFS proposed rule, we sought information from the public regarding ways that we might further expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies. Commenters were very supportive of CMS expanding access to these kinds of services. Many

commenters noted that Medicare payment for telehealth services is restricted by statute, but encouraged CMS to recognize and support technological developments in healthcare.

We believe that the provisions in section 1834(m) of the Act apply particularly to the kinds of professional services explicitly enumerated in the statutory provisions, like professional consultations, office visits, and office psychiatry services. Generally, the services we have added to the telehealth list are similar to these kinds of services. As has long been the case, certain other kinds of services that are furnished remotely using communications technology are not considered “Medicare telehealth services” and are not subject to the restrictions articulated in section 1834(m) of the Act. This is true for services that were routinely paid separately prior to the enactment of the provisions in section 1834(m) of the Act and do not usually include patient interaction (such as remote interpretation of diagnostic imaging tests), and for services that were not discretely defined or separately paid for at the time of enactment and that do include patient interaction (such as chronic care management services).

As we considered the concerns expressed by commenters about the statutory restrictions on Medicare telehealth services, we recognized that the concerns were not limited to the barriers to payment for remotely furnished services like those described by the office visit codes. The commenters also expressed concerns pertaining to the limitations on appropriate payment for evolving physicians’ services that are inherently furnished via communication technology, especially as technology and its uses have evolved in the decades since the Medicare telehealth services statutory provision was enacted.

In recent years, we have sought to recognize significant changes in health care practice, especially innovations in the active management and ongoing care of chronically ill patients, and have relied on the medical community to identify and define discrete physicians’ services through the CPT Editorial Panel (82 FR 53163). In response to our comment solicitation on Medicare telehealth services in the CY 2018 PFS proposed rule (82 FR 53012), commenters provided many suggestions for how CMS could expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies, such as waiving portions

of the statutory restrictions using demonstration authority. After considering those comments we recognize that concerns regarding the provisions in section 1834(m) of the Act may have been limiting the degree to which the medical community developed coding for new kinds of services that inherently utilize communication technology. We have come to believe that section 1834(m) of the Act does not apply to all kinds of physicians’ services whereby a medical professional interacts with a patient via remote communication technology. Instead, we believe that section 1834(m) of the Act applies to a discrete set of physicians’ services that ordinarily involve, and are defined, coded, and paid for as if they were furnished during an in-person encounter between a patient and a health care professional.

For CY 2019, we are aiming to increase access for Medicare beneficiaries to physicians’ services that are routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology. Accordingly, we have several proposals for modernizing Medicare physician payment for communication technology-based services, described below. These services would not be subject to the limitations on Medicare telehealth services in section 1834(m) of the Act because, as we have explained, we do not consider them to be Medicare telehealth services; instead, they would be paid under the PFS like other physicians’ services. Additionally, we note that in furnishing these proposed services, practitioners would need to comply with any applicable privacy and security laws, including the HIPAA Privacy Rule.

1. Brief Communication Technology-Based Service, *e.g.*, Virtual Check-In (HCPCS Code GVC11)

The traditional office visit codes describe a broad range of physicians’ services. Historically, we have considered any routine non-face-to-face communication that takes place before or after an in-person visit to be bundled into the payment for the visit itself. In recent years, we have recognized payment disparities that arise when the amount of non-face-to-face work for certain kinds of patients is disproportionately higher than for others, and created coding and separate payment to recognize care management services such as chronic care management and behavioral health integration services (81 FR 80226). We

now recognize that advances in communication technology have changed patients’ and practitioners’ expectations regarding the quantity and quality of information that can be conveyed via communication technology. From the ubiquity of synchronous, audio/video applications to the increased use of patient-facing health portals, a broader range of services can be furnished by health care professionals via communication technology as compared to 20 years ago.

Among these services are the kinds of brief check-in services furnished using communication technology that are used to evaluate whether or not an office visit or other service is warranted. When these kinds of check-in services are furnished prior to an office visit, then we would currently consider them to be bundled into the payment for the resulting visit, such as through an evaluation and management (E/M) visit code. However, in cases where the check-in service does not lead to an office visit, then there is no office visit with which the check-in service can be bundled. To the extent that these kinds of check-ins become more effective at addressing patient concerns and needs using evolving technology, we believe that the overall payment implications of considering the services to be broadly bundled becomes more problematic. This is especially true in a resource-based relative value payment system. Effectively, the better practitioners are in leveraging technology to furnish effective check-ins that mitigate the need for potentially unnecessary office visits, the fewer billable services they furnish. Given the evolving technological landscape, we believe this creates incentives that are inconsistent with current trends in medical practice and potentially undermines payment accuracy.

Therefore, we are proposing to pay separately, beginning January 1, 2019, for a newly defined type of physicians’ service furnished using communication technology. This service would be billable when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology, to assess whether the patient’s condition necessitates an office visit. We understand that the kinds of communication technology used to furnish these kinds of services has broadened over time and has enhanced the capacity for medical professionals to care for patients. We are seeking comment on what types of communication technology are utilized by physicians or other qualified health care professionals in furnishing these

services, including whether audio-only telephone interactions are sufficient compared to interactions that are enhanced with video or other kinds of data transmission.

The proposed code would be described as GVC11 (Brief communication technology-based service, *e.g.*, virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion). We further propose that in instances when the brief communication technology-based service originates from a related E/M service provided within the previous 7 days by the same physician or other qualified health care professional, that this service would be considered bundled into that previous E/M service and would not be separately billable, which is consistent with code descriptor language for CPT code 99441 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion) on which this service is partially modeled. We propose that in instances when the brief communication technology-based service leads to an E/M in-person service with the same physician or other qualified health care professional, this service would be considered bundled into the pre- or post-visit time of the associated E/M service, and therefore, would not be separately billable. We also note that this service could be used as part of a treatment regimen for opioid use disorders and other substance use disorders, since there are several components of Medication Assisted Therapy (MAT) that could be done virtually, or to assess whether the patient's condition requires an office visit.

We propose pricing this distinct service at a rate lower than existing E/M in-person visits to reflect the low work time and intensity and to account for the resource costs and efficiencies associated with the use of communication technology. We expect that these services would be initiated by

the patient, especially since many beneficiaries would be financially liable for sharing in the cost of these services. For the same reason, we believe it is important for patients to consent to receiving these services, and we are specifically seeking comment on whether we should require, for example, verbal consent that would be noted in the medical record for each service. We are also proposing that this service can only be furnished for established patients because we believe that the practitioner needs to have an existing relationship with the patient, and therefore, basic knowledge of the patient's medical condition and needs, in order to perform this service. We are not proposing to apply a frequency limit on the use of this code by the same practitioner with the same patient, but we want to ensure that this code is appropriately utilized for circumstances when a patient needs a brief non-face-to-face check-in to assess whether an office visit is necessary. We are seeking comment on whether it would be clinically appropriate to apply a frequency limitation on the use of this code by the same practitioner with the same patient, and on what would be a reasonable frequency limitation. We are also seeking comment on the timeframes under which this service would be separately billable compared to when it would be bundled. We believe the general construct of bundling the services that lead directly to a billable visit is important, but we are concerned that establishing strict timeframes may create unintended consequences regarding scheduling of care. For example, we do not want to bundle only the services that occur within 24 hours of a visit only to see a significant number of visits occurring at 25 hours after the initial service. In order to mitigate these incentives, we are seeking comment on whether we should consider broadening the window of time and/or circumstances in which this service should be bundled into the subsequent related visit. We note that these services, like any other physicians' service, would need to be medically reasonable and necessary in order to be paid by Medicare. We are seeking comment on how clinicians could best document the medical necessity of this service, consistent with documentation requirements necessary to demonstrate the medical necessity of any service under the PFS. For details related to developing utilization estimates for these services, see section VII. Regulatory Impact Analysis, of this proposed rule. For additional details related to valuation of these services,

see section II.H. Valuation of Specific Codes, of this proposed rule. We are seeking comment on our proposed definition and valuation of this code.

2. Remote Evaluation of Pre-Recorded Patient Information (HCPCS Code GRAS1)

Stakeholders have requested that CMS make separate Medicare payment when a physician uses recorded video and/or images captured by a patient in order to evaluate a patient's condition. These services involve what is referred to under section 1834(m) of the Act as "store-and-forward" communication technology that provides for the "asynchronous transmission of health care information." We note that we believe these services involve pre-recorded patient-generated still or video images. Other types of patient-generated information, such as information from heart rate monitors or other devices that collect patient health marker data, could potentially be reported with CPT codes that describe remote patient monitoring. Under section 1834(m) of the Act, payment for telehealth services furnished using such store-and-forward technology is permitted only under Federal telemedicine demonstration programs conducted in Alaska or Hawaii, and these telehealth services remain subject to the other statutory restrictions governing Medicare telehealth services. Much like the virtual check-in described above, these services are not meant to substitute for an in-person service currently separately payable under the PFS, and therefore, are distinct from the telehealth services described under section 1834(m) of the Act. Effective January 1, 2019, we are proposing to create specific coding that describes the remote professional evaluation of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology. These services would not be subject to the Medicare telehealth restrictions in section 1834(m) of the Act, and the valuation would reflect the resource costs associated with furnishing services utilizing communication technology.

Much like the brief communication technology-based services discussed above, these services may be used to determine whether or not an office visit or other service is warranted. When the review of the patient-submitted image and/or video results in an in-person E/M office visit with the same physician or qualified health care professional, we propose that this remote service would be considered bundled into that office visit and therefore would not be separately billable. We further propose

that in instances when the remote service originates from a related E/M service provided within the previous 7 days by the same physician or qualified health care professional, that this service would be considered bundled into that previous E/M service and also would not be separately billable. In summary, we propose this service to be a stand-alone service that could be separately billed to the extent that there is no resulting E/M office visit and there is no related E/M office visit within the previous 7 days of the remote service being furnished. The proposed coding and separate payment for this service is consistent with the progression of technology and its impact on the practice of medicine in recent years, and would result in increased access to services for Medicare beneficiaries. The proposed code for this service would be described as GRAS1 (Remote evaluation of recorded video and/or images submitted by the patient (*e.g.*, store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment). We are seeking comment as to whether these services should be limited to established patients; or whether there are certain cases, like dermatological or ophthalmological services, where it might be appropriate for a new patient to receive these services. For example, when a patient seeks care for a specific skin condition from a dermatologist with whom she does not have a prior relationship, and part of the inquiry is an assessment of whether the patient needs an in-person visit, the patient could share, and the dermatologist could remotely evaluate, pre-recorded information. We also note that this service is distinct from the brief communication technology-based service described above in that this service involves the practitioner's evaluation of a patient-generated still or video image, and the subsequent communication of the resulting response to the patient, while the brief communication technology-based service describes a service that occurs in real time and does not involve the transmission of any recorded image.

For details related to developing utilization estimates for these services, see section VII. Regulatory Impact Analysis, of this proposed rule. For further discussion related to valuation of this service, please see the section II.H. Valuation of Specific Codes, of this proposed rule. We are seeking public

comment on our proposed definition and valuation of the code.

3. Interprofessional Internet Consultation (CPT Codes 994X6, 994X0, 99446, 99447, 99448, and 99449)

As part of our standard rulemaking process, we received recommendations from the RUC to assist in establishing values for six CPT codes that describe interprofessional consultations. In 2013, CMS received recommendations from the RUC for CPT codes 99446 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5–10 minutes of medical consultative discussion and review), 99447 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11–20 minutes of medical consultative discussion and review), 99448 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21–30 minutes of medical consultative discussion and review), and 99449 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review). CMS declined to make separate payment, stating in the CY 2014 PFS final rule with comment period that these kinds of services are considered bundled (78 FR 74343). For CY 2019, the CPT Editorial Panel created two new codes to describe additional consultative services, including a code describing the work of the treating physician when initiating a consult, and the RUC recommended valuation for new codes, CPT codes 994X0 (Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes) and 994X6 (Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician

or other qualified health care professional, 5 or more minutes of medical consultative time). The RUC also reaffirmed their prior recommendations for the existing CPT codes. The six codes describe assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis and/or management of the patient's problem without the need for the patient's face-to-face contact with the consulting physician or qualified healthcare professional. Currently, the resource costs associated with seeking or providing such a consultation are considered bundled, which in practical terms means that specialist input is often sought through scheduling a separate visit for the patient when a phone or internet-based interaction between the treating practitioner and the consulting practitioner would have been sufficient. We believe that proposing payment for these interprofessional consultations performed via communications technology such as telephone or internet is consistent with our ongoing efforts to recognize and reflect medical practice trends in primary care and patient-centered care management within the PFS.

Beginning in the CY 2012 PFS proposed rule (76 FR 42793), we have recognized the changing focus in medical practice toward managing patients' chronic conditions, many of which particularly challenge the Medicare population, including heart disease, diabetes, respiratory disease, breast cancer, allergies, Alzheimer's disease, and factors associated with obesity. We have expressed concerns that the current E/M coding does not adequately reflect the changes that have occurred in medical practice, and the activities and resource costs associated with the treatment of these complex patients in the primary care setting. In the years since 2012, we have acknowledged the shift in medical practice away from an episodic treatment-based approach to one that involves comprehensive patient-centered care management, and have taken steps through rulemaking to better reflect that approach in payment under the PFS. In CY 2013, we established new codes to pay separately for transitional care management (TCM)

services. Next, we finalized new coding and separate payment beginning in CY 2015 for chronic care management (CCM) services provided by clinical staff (81 FR 80226). In the CY 2017 PFS final rule, we established separate payment for complex CCM services, an add-on code to the visit during which CCM is initiated to reflect the work of the billing practitioner in assessing the beneficiary and establishing the CCM care plan, and established separate payment for Behavioral Health Integration (BHI) services (81 FR 80226 through 80227).

As part of this shift in medical practice, and with the proliferation of team-based approaches to care that are often facilitated by electronic medical record technology, we believe that making separate payment for interprofessional consultations undertaken for the benefit of treating a patient will contribute to payment accuracy for primary care and care management services. We are proposing separate payment for these services, discussed in section II.H. Valuation of Specific Codes, of this proposed rule.

While we are proposing to make separate payment for these services because we believe they describe resource costs directly associated with seeking a consultation for the benefit of the beneficiary, we do have concerns about how these services can be distinguished from activities undertaken for the benefit of the practitioner, such as information shared as a professional courtesy or as continuing education. We do not believe that those examples would constitute a service directly attributable to a single Medicare beneficiary, and therefore neither the Medicare program nor the beneficiary should be responsible for those costs. We are therefore seeking comment on our assumption that these are separately identifiable services, and the extent to which they can be distinguished from similar services that are nonetheless primarily for the benefit of the practitioner. We note that there are program integrity concerns around making separate payment for these interprofessional consultation services, including around CMS' or its contractors' ability to evaluate whether an interprofessional consultation is reasonable and necessary under the particular circumstances. We are seeking comment on how best to minimize potential program integrity issues, and are particularly interested in information on whether these types of services are paid separately by private payers and if so, what controls or limitations private payers have put in

place to ensure these services are billed appropriately.

Additionally, since these codes describe services that are furnished without the beneficiary being present, we are proposing to require the treating practitioner to obtain verbal beneficiary consent in advance of these services, which would be documented by the treating practitioner in the medical record, similar to the conditions of payment associated with the care management services under the PFS. Obtaining advance consent includes ensuring that the patient is aware of applicable cost sharing. We welcome comments on this proposal.

4. Medicare Telehealth Services Under Section 1834(m) of the Act

a. Billing and Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. For further details, see the full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006).

b. Adding Services to the List of Medicare Telehealth Services

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services in accordance with section 1834(m)(4)(F)(ii) of the Act. This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us. Under this process, we assign any submitted request to add to the list of telehealth services to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.

- *Category 2:* Services that are not similar to those on the current list of

telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

The list of telehealth services, including the proposed additions described below, is included in the Downloads section to this proposed rule at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

Historically, requests to add services to the list of Medicare telehealth services had to be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. However, for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC. To be considered during PFS rulemaking for CY 2020, requests to add services to the list of Medicare telehealth services must be submitted and received by February 10, 2019. Each request to add a service to the list of Medicare telehealth

services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the list of Medicare telehealth services, requesters should be advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the list of Medicare telehealth services, including where to mail these requests, see our website at <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html>.

c. Submitted Requests To Add Services to the List of Telehealth Services for CY 2019

Under our current policy, we add services to the telehealth list on a Category 1 basis when we determine that they are similar to services on the existing telehealth list for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

We received several requests in CY 2017 to add various services as Medicare telehealth services effective for CY 2019. The following presents a discussion of these requests, and our proposals for additions to the CY 2019 telehealth list. Of the requests received, we found that two services were sufficiently similar to services currently on the telehealth list to be added on a Category 1 basis. Therefore, we are proposing to add the following services to the telehealth list on a Category 1 basis for CY 2019:

- HCPCS codes G0513 and G0514 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service) and (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to

code G0513 for additional 30 minutes of preventive service).

We found that the services described by HCPCS codes G0513 and G0514 are sufficiently similar to office visits currently on the telehealth list. We believe that all the components of this service can be furnished via interactive telecommunications technology. Additionally, we believe that adding these services to the telehealth list would make it administratively easier for practitioners who report these services in connection with a preventive service that is furnished via telehealth, as both the base code and the add-on code would be reported with the telehealth place of service.

We also received requests to add services to the telehealth list that do not meet our criteria for Medicare telehealth services. We are not proposing to add to the Medicare telehealth services list the following procedures for chronic care remote physiologic monitoring, interprofessional internet consultation, and initial hospital care; or to change the requirements for subsequent hospital care or subsequent nursing facility care, for the reasons noted in the paragraphs that follow.

(1) Chronic Care Remote Physiologic Monitoring: CPT Codes

- CPT code 990X0 (Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment).
- CPT code 990X1 (Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days).
- CPT code 994X9 (Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month).

In the CY 2016 PFS final rule with comment period (80 FR 71064), we responded to a request to add CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/

decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored) to the Medicare telehealth list. We discussed that the services described by CPT code 99490 can be furnished without the beneficiary's face-to-face presence and using any number of non-face-to-face means of communication. We stated that it was therefore unnecessary to add that service to the list of Medicare telehealth services. Similarly, CPT codes 990X0, 990X1, and 994X9 describe services that are inherently non face-to-face. As discussed in section II.H. Valuation of Specific Codes, we instead are proposing to adopt CPT codes 990X0, 990X1, and 994X9 for payment under the PFS. Because these codes describe services that are inherently non face-to-face, we do not consider them Medicare telehealth services under section 1834(m) of the Act; therefore, we are not proposing to add them to the list of Medicare telehealth services.

(2) Interprofessional Internet Consultation: CPT Codes

- CPT code 994X0 (Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes).
- CPT code 994X6 (Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time).

As discussed in section II.H. Valuation of Specific Codes, we are proposing to adopt CPT codes 994X0 and 994X6 for payment under the PFS as these are distinct services furnished via communication technology. Because these codes describe services that are inherently non face-to-face, we do not consider them as Medicare telehealth services under section 1834(m) of the Act; therefore we are not proposing to add them to the list of Medicare telehealth services for CY 2019.

(3) Initial Hospital Care Services: CPT Codes

- CPT code 99221 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care

with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity.)

- CPT code 99222 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity.)

- CPT code 99223 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity.)

We have previously considered requests to add these codes to the telehealth list. As we stated in the CY 2011 PFS final rule with comment period (75 FR 73315), while initial inpatient consultation services are currently on the list of approved telehealth services, there are no services on the current list of telehealth services that resemble initial hospital care for an acutely ill patient by the admitting practitioner who has ongoing responsibility for the patient's treatment during the course of the hospital stay. Therefore, consistent with prior rulemaking, we do not propose that initial hospital care services be added to the Medicare telehealth services list on a category 1 basis.

The initial hospital care codes describe the first visit of the hospitalized patient by the admitting practitioner who may or may not have seen the patient in the decision-making phase regarding hospitalization. Based on the description of the services for these codes, we believed it is critical that the initial hospital visit by the admitting practitioner be conducted in person to ensure that the practitioner

with ongoing treatment responsibility comprehensively assesses the patient's condition upon admission to the hospital through a thorough in-person examination. Additionally, the requester submitted no additional research or evidence that the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient; therefore, we also do not propose adding initial hospital care services to the Medicare telehealth services list on a Category 2 basis.

We note that Medicare beneficiaries who are being treated in the hospital setting can receive reasonable and necessary E/M services using other HCPCS codes that are currently on the Medicare telehealth list, including those for subsequent hospital care, initial and follow-up telehealth inpatient and emergency department consultations, as well as initial and follow-up critical care telehealth consultations.

Therefore, we are not proposing to add the initial hospital care services to the list of Medicare telehealth services for CY 2019.

(4) Subsequent Hospital Care Services: CPT Codes

- CPT code 99231 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.)

- CPT code 99232 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; an expanded problem focused examination; medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the

bedside and on the patient's hospital floor or unit.)

- CPT code 99233 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; a detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.)

CPT codes 99231–99233 are currently on the list of Medicare telehealth services, but can only be billed via telehealth once every 3 days. The requester asked that we remove the frequency limitation. We stated in the CY 2011 PFS final rule with comment period (75 FR 73316) that, while we still believed the potential acuity of hospital inpatients is greater than those patients likely to receive Medicare telehealth services that were on the list at that time, we also believed that it would be appropriate to permit some subsequent hospital care services to be furnished through telehealth in order to ensure that hospitalized patients have frequent encounters with their admitting practitioner. We also noted that we continue to believe that the majority of these visits should be in-person to facilitate the comprehensive, coordinated, and personal care that medically volatile, acutely ill patients require on an ongoing basis. Because of our concerns regarding the potential acuity of hospital inpatients, we finalized the addition of CPT codes 99231–99233 to the list of Medicare telehealth services, but limited the provision of these subsequent hospital care services through telehealth to once every 3 days. We continue to believe that admitting practitioners should continue to make appropriate in-person visits to all patients who need such care during their hospitalization. Our concerns and position on the provision of subsequent hospital care services via telehealth have not changed. Therefore, we are not proposing to remove the frequency limitation on these codes.

(5) Subsequent Nursing Facility Care Services: CPT Codes

- CPT code 99307 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key

components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 10 minutes are spent at the bedside and on the patient's facility floor or unit.)

- CPT code 99308 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; an expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 15 minutes are spent at the bedside and on the patient's facility floor or unit.)

- CPT code 99309 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; a detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient has developed a significant complication or a significant new problem. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.)

- CPT code 99310 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A comprehensive interval history; a comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 35 minutes are spent at the

bedside and on the patient's facility floor or unit.)

CPT codes 99307–99310 are currently on the list of Medicare telehealth services, but can only be billed via telehealth once every 30 days. The requester asked that we remove the frequency limitation when these services are provided for psychiatric care. We stated in the CY 2011 PFS final rule with comment period (75 FR 73317) that we believed it would be appropriate to permit some subsequent nursing facility care services to be furnished through telehealth to ensure that complex nursing facility patients have frequent encounters with their admitting practitioner, but because of our concerns regarding the potential acuity and complexity of SNF inpatients, we limited the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days. Since these codes are used to report care for patients with a variety of diagnoses, including psychiatric diagnoses, we do not think it would be appropriate to remove the frequency limitation only for certain diagnoses. The services described by these CPT codes are essentially the same service, regardless of the patient's diagnosis. We also continue to have concerns regarding the potential acuity and complexity of SNF inpatients, and therefore, we are not proposing to remove the frequency limitation for subsequent nursing facility care services in CY 2019.

In summary, we are proposing to add the following codes to the list of Medicare telehealth services beginning in CY 2019 on a category 1 basis:

- HCPCS code G0513 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service)).

- HCPCS code G0514 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code G0513 for additional 30 minutes of preventive service)).

5. Expanding the Use of Telehealth Under the Bipartisan Budget Act of 2018

a. Expanding Access to Home Dialysis Therapy Under the Bipartisan Budget Act of 2018

Section 50302 of the BBA of 2018 amended sections 1881(b)(3) and

1834(m) of the Act to allow an individual determined to have end-stage renal disease receiving home dialysis to choose to receive certain monthly end-stage renal disease-related (ESRD-related) clinical assessments via telehealth on or after January 1, 2019. The new section 1881(b)(3)(B)(ii) of the Act requires that such an individual must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.

As added by section 50302(b)(1) of the BBA of 2018, subclauses (IX) and (X) of section 1834(m)(4)(C)(ii) of the Act include a renal dialysis facility and the home of an individual as telehealth originating sites but only for the purposes of the monthly ESRD-related clinical assessments furnished through telehealth provided under section 1881(b)(3)(B) of the Act. Section 50302(b)(1) also added a new section 1834(m)(5) of the Act which provides that the geographic requirements for telehealth services under section 1834(m)(4)(C)(i) of the Act do not apply to telehealth services furnished on or after January 1, 2019 for purposes of the monthly ESRD-related clinical assessments where the originating site is a hospital-based or critical access hospital-based renal dialysis center, a renal dialysis facility, or the home of an individual. Section 50302(b)(2) of the BBA of 2018 amended section 1834(m)(2)(B)(ii) of the Act to require that no originating site facility fee is to be paid if the home of the individual is the originating site.

Our current regulation at § 410.78 specifies the conditions that must be met in order for Medicare Part B to pay for covered telehealth services included on the telehealth list when furnished by an interactive telecommunications system. In accordance with the new subclauses (IX) and (X) of section 1834(m)(4)(C)(ii) of the Act, we are proposing to revise our regulation at § 410.78(b)(3) to add a renal dialysis facility and the home of an individual as Medicare telehealth originating sites, but only for purposes of the home dialysis monthly ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act. We propose to amend § 414.65(b)(3) to reflect the requirement in section 1834(m)(2)(B)(ii) of the Act that there is no originating site facility fee paid when the originating site for these services is the patient's home. Additionally, we are proposing to add new § 410.78(b)(4)(iv)(A), to reflect the provision in section 1834(m)(5) of the Act, added by section 50302 of the BBA

of 2018, specifying that the geographic requirements described in section 1834(m)(4)(C)(i) of the Act do not apply with respect to telehealth services furnished on or after January 1, 2019, in originating sites that are hospital-based or critical access hospital-based renal dialysis centers, renal dialysis facilities, or the patient's home, respectively under sections 1834(m)(4)(C)(ii)(VI), (IX) and (X) of the Act, for purposes of section 1881(b)(3)(B) of the Act.

b. Expanding the Use of Telehealth for Individuals With Stroke Under the Bipartisan Budget Act of 2018

Section 50325 of the BBA of 2018 amended section 1834(m) of the Act by adding a new paragraph (6) that provides special rules for telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke (acute stroke telehealth services), as determined by the Secretary. Specifically, section 1834(m)(6)(A) of the Act removes the restrictions on the geographic locations and the types of originating sites where acute stroke telehealth services can be furnished. Section 1834(m)(6)(B) of the Act specifies that acute stroke telehealth services can be furnished in any hospital, critical access hospital, mobile stroke units (as defined by the Secretary), or any other site determined appropriate by the Secretary, in addition to the current eligible telehealth originating sites. Section 1834(m)(6)(C) of the Act limits payment of an originating site facility fee to acute stroke telehealth services furnished in sites that meet the usual telehealth restrictions under section 1834(m)(4)(C) of the Act.

To implement these requirements, we are proposing to create a new modifier that would be used to identify acute stroke telehealth services. The practitioner and, as appropriate, the originating site, would append this modifier when clinically appropriate to the HCPCS code when billing for an acute stroke telehealth service or an originating site facility fee, respectively. We note that section 50325 of the BBA of 2018 did not amend section 1834(m)(4)(F) of the Act, which limits the scope of telehealth services to those on the Medicare telehealth list. Practitioners would be responsible for assessing whether it would be clinically appropriate to use this modifier with codes from the Medicare telehealth list. By billing with this modifier, practitioners would be indicating that the codes billed were used to furnish telehealth services for diagnosis, evaluation, or treatment of symptoms of

an acute stroke. We believe that the adoption of a service level modifier is the least administratively burdensome means of implementing this provision for practitioners, while also allowing CMS to easily track and analyze utilization of these services.

In accordance with section 1834(m)(6)(B) of the Act, as added by section 50325 of the BBA of 2018, we are also proposing to revise § 410.78(b)(3) of our regulations to add mobile stroke unit as a permissible originating site for acute stroke telehealth services. We are proposing to define a mobile stroke unit as a mobile unit that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke and are seeking comment on this definition, as well as additional information on how these units are used in current medical practice. We are therefore proposing that mobile stroke units and the current eligible telehealth originating sites, which include hospitals and critical access hospitals as specified in section 1834(m)(6)(B) of the Act, but excluding renal dialysis facilities and patient homes because they are only allowable originating sites for purposes of home dialysis monthly ESRD-related clinical assessments in section 1881(b)(3)(B) of the Act, would be permissible originating sites for acute stroke telehealth services.

We also seek comment on other possible appropriate originating sites for telehealth services furnished for the diagnosis, evaluation, or treatment of symptoms of an acute stroke. Any additional sites would be adopted through future rulemaking. As required under section 1834(m)(6)(C) of the Act, the originating site facility fee would not apply in instances where the originating site does not meet the originating site type and geographic requirements under section 1834(m)(4)(C) of the Act. Additionally, we are proposing to add § 410.78(b)(4)(iv)(B) to specify that the requirements in section 1834(m)(4)(C) of the Act do not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

6. Modifying § 414.65 Regarding List of Telehealth Services

In the CY 2015 PFS final rule with comment period, we finalized a proposal to change our regulation at § 410.78(b) by deleting the description of the individual services for which Medicare payment can be made when furnished via telehealth, noting that we revised § 410.78(f) to indicate that a list of Medicare telehealth codes and

descriptors is available on the CMS website (79 FR 67602). In accordance with that change, we are proposing a technical revision to also delete the description of individual services and exceptions for Medicare payment for telehealth services in § 414.65, by amending § 414.65(a) to note that Medicare payment for telehealth services is addressed in § 410.78 and by deleting § 414.65(a)(1).

7. Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders

There is an evidence base that suggests that routine counseling, either associated with medication assisted treatment (MAT) or on its own, can increase the effectiveness of treatment for substance use disorders (SUDs). According to a study in the *Journal of Substance Abuse Treatment*,¹ patients treated with a combination of web-based counseling as part of a substance abuse treatment program demonstrated increased treatment adherence and satisfaction. The federal guidelines for opioid treatment programs describe that MAT and wrap-around psychosocial and support services can include the following services: Physical exam and assessment; psychosocial assessment; treatment planning; counseling; medication management; drug administration; comprehensive care management and supportive services; care coordination; management of care transitions; individual and family support services; and health promotion (<https://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf>). Creating separate payment for a bundled episode of care for components of MAT such as management and counseling treatment for substance use disorders (SUD), including opioid use disorder, treatment planning, and medication management or observing drug dosing for treatment of SUDs under the PFS could provide opportunities to better leverage services furnished with communication technology while expanding access to treatment for SUDs.

We also believe making separate payment for a bundled episode of care for management and counseling for SUDs could be effective in preventing the need for more acute services. For example, according to the *Healthcare*

¹ Van L. King, Robert K. Brooner, Jessica M. Peirce, Ken Kolodner, Michael S. Kidorf, "A randomized trial of Web based videoconferencing for substance abuse counseling," *Journal of Substance Abuse Treatment*, Volume 46, Issue 1, 2014, Pages 36–42, <http://www.sciencedirect.com/science/article/pii/S0740547213001876>.

Cost and Utilization Project,² Medicare pays for one-third of opioid-related hospital stays, and Medicare has seen the largest annual increase in the number of these stays over the past 2 decades. We believe that separate payment for a bundled episode of care could help avoid such hospital admissions by supporting access to management and counseling services that could be important in preventing hospital admissions and other acute care events.

As indicated above, we are considering whether it would be appropriate to develop a separate bundled payment for an episode of care for treatment of SUDs. We are seeking public comment on whether such a bundled episode-based payment would be beneficial to improve access, quality and efficiency for SUD treatment. Further, we are seeking public comment on developing coding and payment for a bundled episode of care for treatment for SUDs that could include overall treatment management, any necessary counseling, and components of a MAT program such as treatment planning, medication management, and observation of drug dosing. Specifically, we are seeking public comments related to what assumptions we might make about the typical number of counseling sessions as well as the duration of the service period, which types of practitioners could furnish these services, and what components of MAT could be included in the bundled episode of care. We are interested in stakeholder feedback regarding how to define and value this bundle and what conditions of payment should be attached. Additionally, we are seeking comment on whether the concept of a global period, similar to the currently existing global periods for surgical procedures, might be applicable to treatment for SUDs.

We also seek comment on whether the counseling portion and other MAT components could also be provided by qualified practitioners “incident to” the services of the billing physician who would administer or prescribe any necessary medications and manage the overall care, as well as supervise any other counselors participating in the treatment, similar to the structure of the Behavioral Health Integration codes

which include services provided by other members of the care team under the direction of the billing practitioner on an “incident to” basis (81 FR 80231). We welcome comments on potentially creating a bundled episode of care for management and counseling treatment for SUDs, which we will consider for future rulemaking.

Additionally, we invite public comment and suggestions for regulatory and subregulatory changes to help prevent opioid use disorder and improve access to treatment under the Medicare program. We seek comment on methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these non-opioid alternatives including barriers related to payment or coverage. Consistent with our “Patients Over Paperwork” Initiative, we are interested in suggestions to improve existing requirements in order to more effectively address the opioid epidemic.

E. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.H. of this proposed rule, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the RUC, MedPAC, and other stakeholders. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by law. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National

Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Physician Quality Reporting System (PQRS) databases. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians’ services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (<http://www.medpac.gov/docs/default-source/congressional-testimony/testimony-report-to-the-congress-medicare-payment-policy-march-2006.pdf?sfvrsn=0>), MedPAC discussed the importance of appropriately valuing physicians’ services, noting that misvalued services can distort the market for physicians’ services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians’ services under the PFS can become misvalued over time. MedPAC stated, “When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.” We believe services can also become overvalued when PE declines. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE rises.

As MedPAC noted in its March 2009 Report to Congress (<http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf>), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to

²Pamela L. Owens, Ph.D., Marguerite L. Barrett, M.S., Audrey J. Weiss, Ph.D., Raynard E. Washington, Ph.D., and Richard Kronick, Ph.D. “Hospital Inpatient Utilization Related to Opioid Overuse Among Adults 1993–2012,” Statistical Brief #177. Healthcare Cost and Utilization Project (HCUP). July 2014. Agency for Healthcare Research and Quality, Rockville, MD, <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.jsp>.

improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and

appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed approximately 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the CY 2012 PFS final rule with comment period (76 FR 73055 through 73958), we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period, we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called “Harvard-valued codes”). In CY 2009 (73 FR 38589), we requested

recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least \$10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time).

In the CY 2016 PFS final rule with comment period, we finalized for review a list of potentially misvalued services, which included eight codes in the neurostimulators analysis-programming family (CPT codes 95970–95982). We also finalized as potentially misvalued 103 codes identified through our screen of high expenditure services across specialties.

In the CY 2017 PFS final rule, we finalized for review a list of potentially misvalued services, which included eight codes in the end-stage renal disease home dialysis family (CPT codes 90963–90970). We also finalized as potentially misvalued 19 codes identified through our screen for 0-day global services that are typically billed with an evaluation and management (E/M) service with modifier 25.

In the CY 2018 PFS final rule, we finalized arthrodesis of sacroiliac joint (CPT code 27279) as potentially misvalued. Through the use of comment solicitations with regard to specific codes, we also examined the valuations of other services, in addition to, new potentially misvalued code screens (82 FR 53017 through 53018).

3. CY 2019 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. The public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10 of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following: Technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.

- An anomalous relationship between the code being proposed for review and other codes.

- Evidence that technology has changed physician work.

- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.

- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.

- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.

- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the PQRS databases).

- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate whether we proposed each nominated code as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In that year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

We received one submission that nominated several high-volume codes for review under the potentially misvalued code initiative. In their request, the submitter noted a systemic overvaluation of work RVUs in certain procedures and tests based "on a

number of Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC) reports, media reports regarding time inflation of specific services, and the January 19, 2017 Urban Institute report for CMS." The submitter suggested that the times CMS assumes in estimating work RVUs are inaccurate for procedures, especially due to substantial overestimates of preservice and postservice time, including follow-up inpatient and outpatient visits that do not take place. According to the submitter, the time estimates for tests and some other procedures are primarily overstated as part of the intraservice time. Furthermore, the submitter stated that previous RUC reviews of these services did not result in reductions in valuation that adequately reflected reductions in surveyed times.

Based on these analyses, the submitter requested that the codes listed in Table 8 be prioritized for reviewed under the potentially misvalued code initiative.

TABLE 8—PUBLIC NOMINATIONS DUE TO OVERVALUATION

CPT code	Short description
27130	Total hip arthroplasty.
27447	Total knee arthroplasty.
43239	Egd biopsy single/multiple.
45385	Colonoscopy w/lesion removal.
70450	CT head w/o contrast.
93000	Electrocardiogram complete.
93306	Tte w/doppler complete.

Another commenter requested that CPT codes 92992 (Atrial septectomy or septostomy; transvenous method, balloon (*e.g.*, Rashkind type) (includes cardiac catheterization)) and 92993 (Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)) be reviewed under the potentially misvalued code initiative in order to establish national RVU values for these services under the MPFS. These codes are currently priced by the Medicare Administrative Contractors (MACs).

b. Update on the Global Surgery Data Collection

CMS currently bundles payment for postoperative care within 10 or 90 days after many surgical procedures. Historically, we have not collected data on how many postoperative visits are

actually performed during the global period. Section 523 of the MACRA added a new paragraph 1848(c)(8) to the Act, and section 1848(c)(8)(B) required CMS to use notice and comment rulemaking to implement a process to collect data on the number and level of postoperative visits and use these data to assess the accuracy of global surgical package valuation. In the CY 2017 PFS final rule, we adopted a policy to collect postoperative visit data.

Beginning July 1, 2017, CMS required practitioners in groups with 10 or more practitioners in nine states (Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island) to use the no-pay CPT code 99024 (Postoperative follow-up visit, normally included in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason(s) related to the original procedure) to report postoperative visits. Practitioners who only practice in practices with fewer than 10 practitioners are exempted from required reporting, but are encouraged to report if feasible. The 293 procedures for which reporting is required are those furnished by more than 100 practitioners, and either are nationally furnished more than 10,000 times annually or have more than \$10 million in annual allowed charges. A list of the procedures for which reporting is required is updated annually to reflect any coding changes and is posted on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html>.

In these nine states, from July 1, 2017 through December 31, 2017, there were 990,581 postoperative visits reported using CPT code 99024. Of the 32,573 practitioners who furnished at least one of the 293 procedures during this period and who, based on Tax Identification Numbers in claims data, were likely to meet the practice size threshold, only 45 percent reported one or more visit using CPT code 99024 during this 6-month period. The share of practitioners who reported any CPT code 99024 claims varied by specialty. Among surgical oncology, hand surgery, and orthopedic surgeons, reporting rates were 92, 90, and 87 percent, respectively. In contrast, the reporting rate for emergency medicine physicians was 4 percent. (See Table 9.)

TABLE 9—SHARE OF PRACTITIONERS WHO REPORTED ANY CPT CODE 99024 CLAIMS, BY SPECIALTY

Practitioner specialty	Number of practitioners *	Number of reporting practitioners **	Percent reporting
ALL	32,642	14,627	45
Family practice	3,912	707	18
Emergency medicine	3,612	153	4
Physician Assistant	2,751	758	28
Orthopedic surgery	2,725	2,360	87
General surgery	2,317	1,879	81
Nurse Practitioner	2,217	438	20
Internal medicine	1,476	161	11
Ophthalmology	1,319	1,069	81
Urology	1,186	1,014	85
Dermatology	1,025	698	68
Diagnostic radiology	982	34	3
Obstetrics/gynecology	966	612	63
Otolaryngology	872	652	75
Podiatry	761	502	66
Neurosurgery	614	512	83
Cardiology	574	307	53
Neurology	525	19	4
Vascular surgery	405	342	84
Pathologic anatomy, clinical pathology	355	281	79
Thoracic surgery	320	270	84
Gastroenterology	315	6	2
Plastic and reconstructive surgery	303	250	83
Physical medicine and rehabilitation	275	63	23
Anesthesiology	254	73	29
Optometry	247	158	64
Pain Management	247	98	40
Colorectal surgery	225	189	84
Hand surgery	214	193	90
Interventional radiology	201	19	9
Interventional Cardiology	195	114	58
Cardiac surgery	176	148	84
Interventional Pain Management	165	55	33
Surgical oncology	154	141	92
Gynecologist/oncologist	143	121	85
General practice	115	37	32
Peripheral vascular disease, medical or surgical	106	84	79
Nephrology	74	9	12
Critical care	54	34	63
Pediatric medicine	39	4	10
Infectious disease	34	3	9
Maxillofacial surgery	25	18	72
Oral surgery	20	11	55
Osteopathic manipulative therapy	18	6	33
Hematology/oncology	16	5	31
Geriatric medicine	15	2	13
Certified clinical nurse specialist	12	1	8
Unknown physician specialty	12	9	75

* Limited to practitioners who performed at least one of the 293 relevant global procedures and were affiliated with a tax identification number with 10 or more practitioners.

** Practitioners who submitted one or more CPT code 99024 claims between July 1st, 2017 and December 31st, 2017.

The share of practitioners who reported CPT code 99024 on any claims also varied by state as shown in Table 10.

TABLE 10—SHARE OF PRACTITIONERS WHO REPORTED ANY CPT CODE 99024 CLAIMS, BY STATE

State	Percentage of practitioners * reporting **
ALL	45
North Dakota	56

TABLE 10—SHARE OF PRACTITIONERS WHO REPORTED ANY CPT CODE 99024 CLAIMS, BY STATE—Continued

State	Percentage of practitioners * reporting **
Ohio	49
Rhode Island	49
Florida	48
New Jersey	43
Louisiana	42
Kentucky	41

TABLE 10—SHARE OF PRACTITIONERS WHO REPORTED ANY CPT CODE 99024 CLAIMS, BY STATE—Continued

State	Percentage of practitioners * reporting **
Oregon	35
Nevada	30

* Limited to practitioners who performed at least one of the 293 relevant global procedures and were affiliated with a tax identification number with 10 or more practitioners.

** Practitioners who submitted one or more CPT code 99024 claims between July 1st, 2017 and December 31st, 2017.

Among 10-day global procedures performed from July 1, 2017 through December 31, 2017, where it is possible to clearly match postoperative visits to specific procedures, only 4 percent had

one or more matched visit reported with CPT code 99024. The percentage of 10-day global procedures with a matched visit reported with CPT code 99024 varied by specialty. Among procedures with 10-day global periods performed by hand surgeons, critical care, and obstetrics/gynecology 44, 36, and 23

percent, respectively, of procedures had a matched visit reported using CPT code 99024. In contrast, less than 5 percent of 10-day global procedures performed by many other specialties had a matched visit reported using CPT code 99024. (See Table 11.)

TABLE 11—SHARE OF PROCEDURES WITH MATCHED POST-OPERATIVE VISITS

Provider specialty	Number of 10-day global procedures *	Number of 10-day global procedures with 1 or more matched 99024 claims **	Percentage of 10-day global procedures with 1 or more matched 99024 claims **
ALL	436,063	16,802	4
Dermatology	205,594	6,920	3
Physician Assistant	57,749	908	2
Nurse Practitioner	31,937	509	2
Family practice	16,770	629	4
Ophthalmology	16,087	1,239	8
Podiatry	12,639	547	4
General surgery	12,113	2,095	17
Diagnostic radiology	11,650	298	3
Neurology	8,075	68	1
Pain Management	6,923	210	3
Emergency medicine	6,012	209	3
Internal medicine	5,883	201	3
Interventional Pain Management	5,210	106	2
Anesthesiology	4,666	105	2
Otolaryngology	4,598	383	8
Interventional radiology	4,197	89	2
Physical medicine and rehabilitation	3,546	53	1
Vascular surgery	3,447	256	7
Gastroenterology	2,264	7	0
Plastic and reconstructive surgery	1,939	403	21
Colorectal surgery	1,851	83	4
General practice	1,807	45	2
Orthopedic surgery	1,688	318	19
Optometry	1,563	45	3
Urology	1,276	277	22
Neurosurgery	1,148	241	21
Nephrology	1,008	25	2
Obstetrics/gynecology	760	171	23
Cardiology	456	14	3
Surgical oncology	440	41	9
Pathology	395	76	19
Pediatric medicine	323	4	1
Neuropsychiatry	296	2	1
Thoracic surgery	276	40	14
Gynecologist/oncologist	266	47	18
Interventional Cardiology	192	5	3
Peripheral vascular disease, medical or surgical	162	5	3
Cardiac surgery	144	25	17
Hand surgery	124	54	44
Critical care	85	30	35
Infectious disease	67	3	4
Osteopathic manipulative therapy	55	1	2
Psychiatry	44	0	0
Geriatric medicine	43	0	0
Hospitalist	42	0	0
Maxillofacial surgery	37	5	14
Oral surgery	34	1	3
Radiation oncology	31	1	3
Certified clinical nurse specialist	26	2	8
Pulmonary disease	20	2	10
Hematology/oncology	19	0	0
Peripheral vascular disease	17	0	0
Preventive medicine	15	0	0
Pathologic anatomy, clinical pathology	12	1	8

TABLE 11—SHARE OF PROCEDURES WITH MATCHED POST-OPERATIVE VISITS—Continued

Provider specialty	Number of 10-day global procedures*	Number of 10-day global procedures with 1 or more matched 99024 claims**	Percentage of 10-day global procedures with 1 or more matched 99024 claims**
Unknown physician specialty	10	3	30

* Limited to the 293 procedures where postoperative visit reporting is required and to those performed by practitioners who work in practices with 10 or more practitioners. Because matching may be unclear in these circumstances, multiple procedures performed on a single day and procedures with overlapping global periods were excluded.

** Matching was based on patient, service dates, and global period duration.

Among 90-day global procedures performed from July 1, 2017 through December 31, 2017, where it is possible to clearly match postoperative visits to specific procedures, 67 percent had one

or more matched visit reported using CPT code 99024. Again, this rate varied by specialty as shown in Table 12. Under the PFS, procedures with 90-day global periods have more than one

postoperative visit. It should be noted that the rates described in this and prior paragraphs are based on any matched postoperative visit reported using CPT code 99024.

TABLE 12—SHARE OF PROCEDURES WITH MATCHED POST-OPERATIVE VISITS, FOR PROCEDURE CODES WITH 90-DAY GLOBAL PERIODS

Provider specialty	Number of 90-day global procedures*	Number of 90-day global procedures with 1 or more matched 99024 claims**	Percentage of 90-day global procedures with 1 or more matched 99024 claims**
ALL	232,235	156,727	67
Orthopedic surgery	71,991	54,876	76
Ophthalmology	63,333	41,700	66
General surgery	25,593	17,559	69
Pathologic anatomy, clinical pathology	10,149	4,371	43
Urology	8,481	4,828	57
Dermatology	7,692	4,160	54
Neurosurgery	6,993	5,256	75
Cardiology	5,932	2,388	40
Vascular surgery	5,400	3,552	66
Hand surgery	4,783	3,718	78
Thoracic surgery	3,700	2,859	77
Cardiac surgery	2,764	2,183	79
Plastic and reconstructive surgery	2,500	1,670	67
Podiatry	2,383	1,393	58
Otolaryngology	1,692	1,014	60
Physician Assistant	1,492	903	61
Colorectal surgery	1,316	869	66
Interventional Cardiology	1,123	500	45
Peripheral vascular disease, medical or surgical	753	524	70
Obstetrics/gynecology	752	469	62
Surgical oncology	716	511	71
Optometry	402	248	62
Gynecologist/oncologist	322	219	68
Internal medicine	317	133	42
Emergency medicine	258	62	24
Nurse Practitioner	243	153	63
General practice	217	125	58
Gastroenterology	139	13	9
Osteopathic manipulative therapy	131	94	72
Family practice	115	65	57
Critical care	98	77	79
Neurology	87	64	74
Interventional radiology	65	22	34
Unknown physician specialty	60	34	57
Diagnostic radiology	50	6	12
Nephrology	33	21	64
Maxillofacial surgery	29	23	79
Physical medicine and rehabilitation	26	16	62
Interventional Pain Management	14	2	14
Pathology	13	3	23
Hematology/oncology	12	12	100

TABLE 12—SHARE OF PROCEDURES WITH MATCHED POST-OPERATIVE VISITS, FOR PROCEDURE CODES WITH 90-DAY GLOBAL PERIODS—Continued

Provider specialty	Number of 90-day global procedures*	Number of 90-day global procedures with 1 or more matched 99024 claims**	Percentage of 90-day global procedures with 1 or more matched 99024 claims**
Peripheral vascular disease	10	5	50

* Limited to the 293 procedures where post-operative visit reporting is required and to those performed by practitioners who work in practices with 10 or more practitioners. Because matching may be unclear in these circumstances, multiple procedures performed on a single day and procedures with overlapping global periods were excluded.

** Matching was based on patient, service dates, and global period duration.

One potential explanation for these findings is that many practitioners are not consistently reporting postoperative visits using CPT code 99024. We are soliciting suggestions as to how to encourage reporting to ensure the validity of the data without imposing undue burden. Specifically, we are soliciting comments on whether we need to do more to make practitioners aware of their obligation and whether we should consider implementing an enforcement mechanism.

Given the very small number of postoperative visits reported using CPT code 99024 during 10-day global periods, we are seeking comment on whether or not it might be reasonable to assume that many visits included in the valuation of 10-day global packages are not being furnished, or whether there are alternative explanations for what could be a significant level of underreporting of postoperative visits. For example, we are soliciting comments on whether it is likely that in many cases the practitioner reporting the procedure code is not performing the postoperative visit, or if the postoperative visit is being furnished by a different practitioner. Alternatively, we are soliciting comments on whether it is possible that some or all of the postoperative visits are occurring after the global period ends and are, therefore, reported and paid separately.

We conducted an analysis to try to assess the extent of underreporting. We identified a set of “robust reporters” who appeared to be regularly reporting post-operative visits using CPT code 99024. They were defined as practitioners who (a) furnished 10 or more procedures with 90-day global periods where it is possible for us to match specific procedures to reported post-operative visits without ambiguity, and (b) reported a post-operative visit using CPT code 99024 for at least half of these 90-day global procedures. Among this subset of practitioners and procedures, we found that 87 percent of procedures with 90-day global periods

had one or more associated post-operative visits. However, only 16 percent of procedures with a 10-day global period had an associated postoperative visit reported using CPT code 99024. These findings suggest that post-operative visits following procedures with 10-day global periods are not typically being furnished rather than not being reported.

Under current policy, in cases where practitioners agree on the transfer of care for the postoperative portion of the global period, the surgeon bills only for the surgical care using modifier 54 “for surgical care only” and the practitioner who furnishes the postoperative care bills using modifier 55 “postoperative management only.” The global surgery payment is then split between the two practitioners. However, practitioners are not required to report these modifiers unless there is a formal transfer of postoperative care. We are also soliciting comments on whether we should consider requiring use of the modifiers in cases where the surgeon does not expect to perform the postoperative visits, regardless of whether or not the transfer of care is formalized.

We are also seeking comment on the best approach to 10-day global codes for which the preliminary data suggest that postoperative visits are rarely performed by the practitioner reporting the global code. That is, we are seeking comments on whether we should consider changing the global period and reviewing the code valuation.

Finally, we note that claims-based data collection using CPT code 99024 is intended to collect information on the number of post-operative visits but not the level of post-operative visits. We anticipate beginning, in the near future, a separate survey-based data collection effort on the level of post-operative visits including the time, staff, and activities involved in furnishing post-operative visits and non-face-to-face services. The survey component is intended to address concerns from the

physician community that information on the number of visits alone cannot capture differences between specialties, specific procedure codes, and setting in terms of the time and effort spent on post-operative visits and non-face-to-face services included in global periods.

RAND developed a survey that collects information on the time, staff, and activities related to five post-operative visits furnished by sampled practitioners. The CY 2017 PFS final rule (81 FR 80222) described a sampling approach for the survey that would have collected data on post-operative visits related to the full range of procedures with 10-day and 90-day global periods using a stratified random sample of approximately 5,000 practitioners. RAND piloted the post-operative visit survey in a small subsample of practitioners and found a very low response rate. This low response rate raised concerns that the survey would not yield useful or representative information on post-operative visits if the survey were fielded in the full sample.

In an effort to increase response rate and collect sufficient data on the level of visits associated with at least some procedures with 10-day and 90-day global periods, we refocused the survey effort to collect information on post-operative visits and non-face-to-face services associated with a small number of high-volume procedure codes. The survey sampling frame includes practitioners who perform above a threshold volume of the selected high-volume procedure codes. Practitioner participation in the survey-based data collection effort is important to ensure that CMS collects useful and representative data to understand the range of activities, staff, and time involved in furnishing post-operative visits. Future survey-based data collection may cover post-operative visits and non-face-to-face services associated with a broader range of procedures with 10-day and 90-day global periods.

F. Radiologist Assistants

In accordance with § 410.32(b)(3), except as otherwise provided, all diagnostic X-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under at least a general level of physician supervision as defined in paragraph (b)(3)(i) of this regulation. In addition, some of these tests require either direct or personal supervision as defined in paragraph (b)(3)(ii) or (iii) of this regulation, respectively. We list the required minimum physician supervision level for each diagnostic X-ray and other diagnostic test service along with the codes and relative values for these services in the PFS Relative Value File, which is posted on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html>. For most diagnostic imaging procedures, this required physician supervision level applies only to the technical component (TC) of the procedure.

In response to the Request for Information on CMS Flexibilities and Efficiencies (RFI) that was issued in the CY 2018 PFS proposed rule (82 FR 34172 through 34173), many commenters recommended that we revise the physician supervision requirements at § 410.32(b) for diagnostic tests with a focus on those that are typically furnished by a radiologist assistant under the supervision of a physician. Specifically, the commenters stated that all diagnostic tests, when performed by radiologist assistants (RAs), can be furnished under direct supervision rather than personal supervision of a physician, and that we should revise the Medicare supervision requirements so that when RAs conduct diagnostic imaging tests that would otherwise require personal supervision, they only need to do so under direct supervision. In addition to increasing efficiency, stakeholders suggested that the current supervision requirements for certain diagnostic imaging services unduly restrict RAs from conducting tests that they are permitted to do under current law in many states.

After consideration of these comments on the RFI, as well as information provided by stakeholders, we are proposing to revise our regulations to specify that all diagnostic imaging tests may be furnished under the direct supervision of a physician when performed by an RA in accordance with state law and state scope of practice rules. Stakeholders

representing the radiology community have provided us with information showing that the RA designation includes registered radiologist assistants (RRAs) who are certified by The American Registry of Radiologic Technologists, and radiology practitioner assistants (RPAs) who are certified by the Certification Board for Radiology Practitioner Assistants. We are proposing to revise our regulation at § 410.32 to add a new paragraph (b)(4) to state that diagnostic tests performed by an RRA or an RPA require only a direct level of physician supervision, when permitted by state law and state scope of practice regulations. We note that for diagnostic imaging tests requiring a general level of physician supervision, this proposal would not change the level of physician supervision to direct supervision. Otherwise, the diagnostic imaging tests must be performed as specified elsewhere under § 410.32(b). We based this proposal on recommendations from the practitioner community which included specific recommendations on how to implement the change. We received information submitted by representatives of the practitioner community, including information on the education and clinical experience of RAs, which we took into consideration in determining if this proposal would pose a significant risk to patient safety, and we determined that it would not. In addition, we considered information provided by stakeholders that indicates that 28 states have statutes or regulations that recognize RAs, and these states have general or direct supervision requirements for RAs.

G. Payment Rates Under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

1. Background

Sections 1833(t)(1)(B)(v) and (t)(21) of the Act require that certain items and services furnished by certain off-campus provider-based departments (PBDs) (collectively referenced here as nonexcepted items and services furnished by nonexcepted off-campus PBDs) shall not be considered covered outpatient department services for purposes of payment under the Hospital Outpatient Prospective Payment System (OPPS), and payment for those nonexcepted items and services furnished on or after January 1, 2017 shall be made under the applicable payment system under Medicare Part B if the requirements for such payment are otherwise met. These requirements were

enacted in section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74). In the CY 2017 OPPS/Ambulatory Surgical Center (ASC) final rule with comment period (81 FR 79699 through 79719), we established several policies and provisions to define the scope of nonexcepted items and services in nonexcepted off-campus PBDs. We also finalized the PFS as the applicable payment system for most nonexcepted items and services furnished by nonexcepted off-campus PBDs. At the same time, we issued an interim final rule with comment period (81 FR 79720 through 79729) in which we established payment policies under the PFS for nonexcepted items and services furnished on or after January 1, 2017. In the following paragraphs, we summarize the policies that we adopted for CY 2017 and CY 2018, and we propose payment policies for CY 2019. For issues related to the excepted status of off-campus PBDs or the excepted status of items and services, please see the CY 2019 OPPS/ASC proposed rule.

2. Payment Mechanism

In establishing the PFS as the applicable payment system for most nonexcepted items and services in nonexcepted off-campus PBDs under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, we recognized that there was no technological capability, at least in the near term, to allow off-campus PBDs to bill under the PFS for those nonexcepted items and services. Off-campus PBDs bill under the OPPS for their services on an institutional claim, while physicians and other suppliers bill under the PFS on a practitioner claim. The two systems that process these different types of claims, the Fiscal Intermediary Standard System (“FISS”) and the Multi-Carrier System (“MCS”) system, respectively, were not designed to accept or process claims of a different type. To permit an off-campus PBD to bill directly under a different payment system than the OPPS would have required significant changes to these complex systems as well as other systems involved in the processing of Medicare Part B claims. Consequently, we proposed and finalized a policy for CY 2017 and CY 2018 in which nonexcepted off-campus PBDs continue to bill for nonexcepted items and services on the institutional claim utilizing a new claim line modifier “PN” to indicate that an item or service is a nonexcepted item or service.

We implemented requirements under section 1833(t)(1)(B) of the Act for CY 2017 and CY 2018 by applying an overall downward scaling factor, called

the PFS Relativity Adjuster to payments for nonexcepted items and services furnished in nonexcepted off campus PBDs. The PFS Relativity Adjuster generally reflects the average (weighted by claim line volume times rate) of the site-specific rate under the PFS compared to the rate under the OPPS (weighted by claim line volume times rate) for nonexcepted items and services furnished in nonexcepted off-campus PBDs. As we have discussed extensively in prior rulemaking (81 FR 97920 through 97929 and 82 FR 53021), we established a new set of site-specific payment rates under the PFS that reflect the relative resource cost of furnishing the technical component (TC) of services furnished in nonexcepted off-campus PBDs. For the majority of HCPCS codes, these rates are based on either (1) the difference between the PFS nonfacility payment rate and the PFS facility rate, (2) the technical component, or (3) in instances where payment would have been made only to the facility or to the physician, the full nonfacility rate. The PFS Relativity Adjuster refers to the percentage of the OPPS payment amount paid under the PFS for a nonexcepted item or service to the nonexcepted off-campus PBD.

To operationalize the PFS Relativity Adjuster as a mechanism to pay for nonexcepted items and services furnished by nonexcepted off-campus PBDs, we adopted the packaging payment rates and multiple procedure payment reduction (MPPR) percentage that applies under the OPPS. We also incorporated the claims processing logic that is used for payments under the OPPS for comprehensive APCs (C-APCs), conditionally and unconditionally packaged items and services, and major procedures. As we noted in the CY 2017 interim final rule (82 FR 53024), we believe that this maintains the integrity of the cost-specific relativity of current payments under the OPPS compared with those under the PFS.

In CY 2017, we implemented a PFS Relativity Adjuster of 50 percent of the OPPS rate for nonexcepted items and services furnished in nonexcepted off-campus PBDs. For a detailed explanation of how we developed the PFS Relativity Adjuster of 50 percent for CY 2017, including assumptions and exclusions, we refer readers to the CY 2017 OPPS/ASC interim final rule with comment period (81 FR 79720 through 79729). Beginning for CY 2018, we adopted a PFS Relativity Adjuster of 40 percent of the OPPS rate. For a detailed explanation of how we developed the PFS Relativity Adjuster of 40 percent, we refer readers to the CY 2018 PFS

final rule (82 FR 53019 through 53042). A brief overview of the general approach we took for CY 2018 and how it differs from the proposal for CY 2019 appears below.

3. The PFS Relativity Adjuster

The PFS Relativity Adjuster reflects the overall relativity of the applicable payment rate for nonexcepted items and services furnished in nonexcepted off-campus PBDs under the PFS compared with the rate under the OPPS. To develop the PFS Relativity Adjuster for CY 2017, we did not have all of the claims data needed to identify the mix of items and services that would be billed using the “PN” modifier. Instead, we analyzed hospital outpatient claims data from January 1 through August 25, 2016, that contained the “PO” modifier, which was a new mandatory reporting requirement for CY 2016 for claims that were billed by an off-campus department of a hospital. We limited our analysis to those claims billed on the 13X Type of Bill because those claims were used for Medicare Part B billing under the OPPS. We then identified the 25 most frequently billed major codes that were billed by claim line; that is, items and services that were separately payable or conditionally packaged. Specifically, we restricted our analysis to codes with OPPS status indicators (SI) “J1”, “J2”, “Q1”, “Q2”, “Q3”, “S”, “T”, or “V”. The most frequently billed service with the “PO” modifier in CY 2016 was described by HCPCS code G0463 (Hospital outpatient clinic visit for the assessment and management of a patient), which, in CY 2016, was paid under APC 5012 at a rate of \$102.12; the total number of claim lines for this service was approximately 6.7 million as of August 2016. Under the PFS, there are ten CPT codes describing different levels of office visits for new and established payments. We compared the payment rate under OPPS for G0463 (\$102.12) to the average of the difference between the nonfacility and facility rates for CPT code 99213 (Level III office visit for an established patient) and CPT code 99214 (Level IV office visit for an established patient) in CY 2016 and found that the relative payment difference was approximately 22 percent. We did not include HCPCS code G0463 in our calculation of the PFS Relativity Adjuster for CY 2017 because we were concerned that there was no single, directly comparable code under the PFS. As we stated in the CY 2017 interim final rule (81 FR 79723), we wanted to mitigate the risk of underestimating the overall relativity between the PFS and OPPS rates. From the remaining top 24 most frequently

billed codes, we excluded HCPCS code 36591 (Collection of blood specimen from a completely implantable venous access device) because, under PFS policies, the service was only separately payable under the PFS when no other code was on the claim. We also removed HCPCS code G0009 (Administration of Pneumococcal Vaccine) because there was no payment for this code under the PFS. For the remaining top 22 codes furnished with the “PO” modifier in CY 2016, the average (weighted by claim line volume times rate) of the nonfacility payment rate estimate for the PFS compared to the estimate for the OPPS was 45 percent. We indicated that, because of our inability to estimate the effect of the packaging difference between the OPPS and the PFS, we would assume a 5 percentage point adjustment upward from the calculated amount of 45 percent; therefore, we established the PFS Relativity Adjuster of 50 percent for CY 2017.

In establishing the PFS Relativity Adjuster for CY 2018, we still did not have claims data for items and services furnished reported with a “PN” modifier. However, we updated the list of the 25 most frequently billed HCPCS codes using an entire year (CY 2016) of claims data for services submitted with a “PO” modifier and we updated the corresponding utilization weights for the codes used in the analysis. The order and composition of the top 25 separately payable HCPCS codes, based on the full year of claims from CY 2016 submitted with the “PO” modifier, changed minimally from the codes we used in our original analysis for the CY 2017 OPPS/ASC interim final rule with comment period. For a detailed list of the HCPCS codes we used in calculating the CY 2017 PFS Relativity Adjuster and the CY 2018 PFS Relativity Adjuster, we refer readers to the CY 2018 PFS final rule (82 FR 53030 through 53031). As noted earlier, in establishing the PFS Relativity Adjuster of 50 percent for CY 2017, we did not include in the weighted average code comparison, the relative rate for the most frequently billed service furnished in off-campus PBDs, HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), in part to ensure that we were not underestimating the overall relativity between the PFS and the OPPS. In contrast, in the CY 2018 PFS final rule, we stated that our objective for CY 2018 was to ensure that we did not overestimate the appropriate overall payment relativity, and that the payment made to nonexcepted off-campus PBDs better aligned with the

services that are most frequently furnished in the setting. Therefore, in addition to using updated claims data, we revised the PFS Relativity Adjuster to incorporate the relative payment rate for HCPCS code G0463 into our analysis. We followed all other exclusions and assumptions that were made in calculating the CY 2017 PFS Relativity Adjuster. Our analysis resulted in a 35 percent relative difference in payment rates. Similar to our stated rationale in the CY 2017 PFS final rule, we increased the PFS Relativity Adjuster to 40 percent, acknowledging the difficulty of estimating the effect of the packaging differences between the OPPS and the PFS.

4. Proposed Payment Policies for CY 2019

In prior rulemaking, we stated our expectation that our general approach of adjusting OPPS payments using a single scaling factor, the PFS Relativity Adjuster, would continue to be an appropriate payment mechanism to implement provisions of section 603 of the Bipartisan Budget Act of 2015, and would remain in place until we are able to establish code-specific reductions that represent the technical component of services furnished under the PFS or until we are able to implement system changes needed to enable nonexcepted off-campus PBDs to bill for nonexcepted items and services under the PFS directly (82 FR 53029). As we continue to explore alternative options related to requirements under section 1833(t)(21)(C) of the Act, we believe that this overall approach is still appropriate, and we are proposing to continue to allow nonexcepted off-campus PBDs to bill for nonexcepted items and services on an institutional claim using a “PN” modifier until we identify a workable alternative mechanism that would improve payment accuracy.

We made several adjustments to our methodology for calculating the PFS Relativity Adjuster for CY 2019. Most importantly, we had access to a full year of claims data from CY 2017 for services submitted with the “PN” modifier. Incorporating these data allows us to improve the accuracy of the PFS Relativity Adjuster by accounting for the specific mix of nonexcepted items and services furnished in nonexcepted off-campus PBDs. In analyzing the CY 2017 claims data, we identified just under 2,000 unique OPPS HCPCS/SI pairs reported in CY 2017 with status indicators “J1”, “J2”, “Q1”, “Q2”, “Q3”, “S”, “T”, or “V”. The data reinforce our previous observation that

the single most frequently reported service furnished in nonexcepted off-campus PBDs is HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient). Nearly half (49 percent) of all claim lines for separately payable or conditionally packaged services furnished by nonexcepted off-campus PBDs included HCPCS code G0463 in CY 2017, representing 30 percent of total Medicare payments for separately payable or conditionally packaged services. The top 30 HCPCS/SI combinations accounted for 80 percent of all claim lines and approximately 60 percent of Medicare payments for services that are separately billable. In contrast with prior analyses, we also looked at claims units, which reflects HCPCS/SI combinations that are billed more than once on a claim line. Certain HCPCS codes are much more frequently billed in multiple units than others. For instance, HCPCS code G0463, which appears in nearly half of all claim lines, only represents eight percent of all claims units with a SI for separately payable or conditionally packaged services. The largest differences between the number of claim lines and the number of claims units are for injections and immunizations, which are not typically separately payable or conditionally packaged under the OPPS. For instance, HCPCS code Q9967 (Low osmolar contrast material, 300–399 mg/ml iodine concentration, per ml) was reported in 12,268 claim lines, but 1,168,393 times (claims units) in the aggregate. HCPCS code Q9967 has an OPPS status indicator of “N”, meaning that there is no separate payment under OPPS (items and services are packaged into APC rates).

To calculate the PFS Relativity Adjuster using the full range of claims data submitted with a “PN” modifier in CY 2017, we first established site-specific rates under the PFS that reflect the technical component (TC) of items and services furnished by nonexcepted off-campus PBDs in CY 2017. These HCPCS-level rates reflect our best current estimate of the amount that would have been paid for the service in the office setting under the PFS for practice expenses not associated with the professional component of the service. As discussed in prior rulemaking (81 FR 79720 through 79729), we believe the most appropriate code-level comparison would reflect the technical component (TC) of each HCPCS code under the PFS. However, we do not currently calculate a separate TC rate for all HCPCS codes under the PFS—only for those for which the

professional component (PC) and TC of the service are distinct and can be separately billed by two different practitioners or other suppliers under the PFS. For most of the remainder of services that do not have a separately payable TC under the PFS, we estimated the site-specific rate as (1) the difference between the PFS nonfacility rate and the PFS facility rate, or (2) in instances where payment would have been made only to the facility or only to the physician, the full nonfacility rate. As with the PFS rates that we developed when calculating the PFS Relativity Adjuster for CY 2017 and CY 2018, there were large code-level differences between the applicable PFS rate and the OPPS rate.

In calculating the proposed PFS Relativity Adjuster for CY 2019, we employed the same fundamental methodology that we used to calculate the PFS Relativity Adjuster for CY 2017 and CY 2018. We began by limiting our analysis to the items and services billed in CY 2017 with a “PN” modifier that are separately payable or conditionally packaged under the OPPS (SI = “J1”, “J2”, “Q1”, “Q2”, “Q3”, “S”, “T”, or “V”) and compared the rates for these codes under the OPPS with the site-specific rates under the PFS. Next, we imputed PFS rates for a limited number of items and services that are separately payable or conditionally packaged under the OPPS but are contractor priced under the PFS. We also imputed PFS rates for some HCPCS codes that are not separately payable under the OPPS (SI = “N”), but are separately payable under the PFS. This includes items and services with an indicator status of “X” under the PFS, which are statutorily excluded from payment under the PFS, but may be paid under a different fee schedule, such as the Clinical Lab Fee Schedule (CLFS). We summed the HCPCS-level rates under the PFS across all nonexcepted items and services, weighted by the number of HCPCS claims for each service. Next, we calculated the sum of the HCPCS-level OPPS rate for items and services that are separately payable or conditionally packaged, also weighted by the number of HCPCS claims. We compared the weighted sum of the site-specific PFS rate with the weighted sum of the OPPS rate for items and services reported in CY 2017 and we found that our updated analysis supports maintaining a PFS Relativity Adjuster of 40 percent. In view of this analysis, we propose to continue applying a PFS Relativity Adjuster of 40 percent for CY 2019. Moreover, we propose to maintain this PFS Relativity Adjuster for future years

until updated data or other considerations indicate that an alternative adjuster or a change to our approach is warranted, which we would then propose through notice and comment rulemaking. We discuss some of our ongoing data analyses and future plans regarding implementation of section 603 of the Bipartisan Budget Act of 2015 below.

5. Policies Related to Supervision, Beneficiary Cost-Sharing, and Geographic Adjustments

In the CY 2018 PFS final rule (81FR 53019 through 53031), we finalized policies related to supervision rules, beneficiary cost sharing, and geographic adjustments. We finalized that supervision rules in nonexcepted off-campus PBDs that furnish nonexcepted items and services are the same as those that apply for hospitals, in general. We also finalized that all beneficiary cost sharing rules that apply under the PFS in accordance with sections 1848(g) and 1866(a)(2)(A) of the Act continue to apply when payment is made under the PFS for nonexcepted items and services furnished by nonexcepted off-campus PBDs, regardless of cost sharing obligations under the OPPIs. Lastly, we finalized the policy to apply the same geographic adjustments used under the OPPIs to nonexcepted items and services furnished in nonexcepted off-campus PBDs. We note that we are maintaining these policies as finalized in CY 2018 PFS final rule.

6. Partial Hospitalization

a. Partial Hospitalization Services

Partial hospitalization programs (PHPs) are intensive outpatient psychiatric day treatment programs furnished to patients as an alternative to inpatient psychiatric hospitalization, or as a stepdown to shorten an inpatient stay and transition a patient to a less intensive level of care. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital, to its outpatients, or by a Community Mental Health Center (CMHC). In the CY 2017 OPPIs/ASC proposed rule (81 FR 45690), in the discussion of the proposed implementation of section 603 of Bipartisan Budget Act of 2015, we noted that because CMHCs also furnish PHP services and are ineligible to be provider-based to a hospital, a nonexcepted off-campus PBD would be eligible for PHP payment if the entity enrolls and bills as a CMHC for payment under the OPPIs. We further noted that a hospital may choose to enroll a nonexcepted off-campus PBD as a

CMHC, provided it meets all Medicare requirements and conditions of participation.

Commenters expressed concern that without a clear payment mechanism for PHP services furnished by nonexcepted off-campus PBDs, access to partial hospitalization services would be limited, and pointed out the critical role PHPs play in the continuum of mental health care. Many commenters believed that the Congress did not intend for partial hospitalization services to no longer be paid for by Medicare when such services are furnished by nonexcepted off-campus PBDs. Several commenters disagreed with the notion of enrolling as a CMHC in order to receive payment for PHP services. These commenters stated that hospital-based PHPs and CMHCs are inherently different in structure, operation, and payment, and noted that the conditions of participation for hospital departments and CMHCs are different. Several commenters requested that CMS find a mechanism to pay hospital-based PHPs in nonexcepted off-campus PBDs.

Because we shared the commenters' concerns, in the CY 2017 OPPIs/ASC final rule with comment period and interim final rule with comment period (81 FR 79715, 79717, and 79727), we adopted payment for partial hospitalization items and services furnished by nonexcepted off-campus PBDs under the PFS. When billed in accordance with the CY 2017 interim final rule, these partial hospitalization services are paid at the CMHC per diem rate for APC 5853, for providing three or more partial hospitalization services per day (81 FR 79727).

In the CY 2017 OPPIs/ASC proposed rule (81 FR 45681), the CY 2017 OPPIs/ASC final rule with comment period, and the interim final rule with comment period (81 FR 79717 and 79727), we noted that when a beneficiary receives outpatient services in an off-campus department of a hospital, the total Medicare payment for those services is generally higher than when those same services are provided in a physician's office. Similarly, when partial hospitalization services are provided in a hospital-based PHP, Medicare pays more than when those same services are provided by a CMHC. Our rationale for adopting the CMHC per diem rate for APC 5853 as the PFS payment amount for nonexcepted off-campus PBDs providing PHP services is because CMHCs are freestanding entities that are not part of a hospital, but they provide the same PHP services as hospital-based PHPs (81 FR 79727). This is similar to the differences between freestanding entities paid under the PFS that furnish

other services also provided by hospital-based entities. Similar to other entities currently paid for their technical component services under the PFS, we believe CMHCs would typically have lower cost structures than hospital-based PHPs, largely due to lower overhead costs and other indirect costs such as administration, personnel, and security. We believe that paying for nonexcepted hospital-based partial hospitalization services at the lower CMHC per diem rate aligns with section 603 of Bipartisan Budget Act of 2015, while also preserving access to PHP services. In addition, nonexcepted off-campus PBDs will not be required to enroll as CMHCs in order to bill and be paid for providing partial hospitalization services. However, a nonexcepted off-campus PBD that wishes to provide PHP services may still enroll as a CMHC if it chooses to do so and meets the relevant requirements. Finally, we recognize that because hospital-based PHPs are providing partial hospitalization services in the hospital outpatient setting, they can offer benefits that CMHCs do not have, such as an easier patient transition to and from inpatient care, and easier sharing of health information between the PHP and the inpatient staff.

In the CY 2018 PFS final rule, we did not require these PHPs to enroll as CMHCs but instead we continued to pay nonexcepted off-campus PBDs providing PHP items and services under the PFS. Further, in that CY 2018 PFS final rule, we continued to adopt the CMHC per diem rate for APC 5853 as the PFS payment amount for nonexcepted off-campus PBDs providing three or more PHP services per day in CY 2018 (82 FR 53025 to 53026).

For CY 2019, we propose to continue to identify the PFS as the applicable payment system for PHP services furnished by nonexcepted off-campus PBDs, and propose to continue to set the PFS payment rate for these PHP services as the per diem rate that would be paid to a CMHC in CY 2019. We further propose to maintain these policies for future years until updated data or other considerations indicate that a change to our approach is warranted, which we would then propose through notice and comment rulemaking.

7. Future Years

We continue to believe the amendments made by section 603 of the Bipartisan Budget Act of 2015 were intended to eliminate the Medicare payment incentive for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill

under the OPPTS for items and services they furnish there. Therefore, we continue to believe the payment policy under this provision should ultimately equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible, while allowing nonexcepted off-campus PBDs to bill in a straight-forward way for services they furnish.

Under the proposed methodology for CY 2019 as described previously, we use updated claims data for CY 2019, in combination with the expanded number of site specific, technical component rates for nonexcepted items and services furnished in nonexcepted off campus PBDs, in order to ensure that Medicare payment to hospitals billing for nonexcepted items and services furnished by nonexcepted off-campus PBDs reflects the relative resources involved in furnishing the items and services. We recognize that for certain specialties, service lines, and nonexcepted off-campus PBD types, total Medicare payments for the same services might be either higher or lower when furnished by a nonexcepted off-campus PBD rather than in a physician office. We also note that our approach adopts packaging rules and MPPR rules under the OPPTS.

As noted above, we intend to continue to examine the claims data in order to assess whether a different PFS Relativity Adjuster is warranted and also to consider whether additional adjustments to the methodology are appropriate. In particular, we are monitoring claims for shifts in the mix of services furnished in nonexcepted off campus PBDs that may affect the relativity between the PFS and OPPTS. An increase over time in the share of nonexcepted items and services with lower technical component rates under the PFS compared with APC rates under the OPPTS might result in a lower PFS Relativity Adjuster, for example. We will also carefully assess annual payment policy updates to the PFS and OPPTS fee schedule rules, respectively, to identify changes in overall relativity resulting from any new or modified policies such as expanded packaging under the OPPTS or an increase in the number of HCPCS codes with global periods under the PFS. As part of these ongoing efforts, we are also analyzing PFS claims data to identify patterns of services furnished together on the same day. We anticipate that this will ultimately allow us to make refinements to the PFS Relativity Adjuster to better account for the more extensive packaging of services under the OPPTS and the potential underreporting of services that are not separately payable

under the OPPTS but are paid separately under the PFS.

Another dimension of our ongoing efforts to improve implementation of section 603 of the Bipartisan Budget Act of 2015 is the development and refinement of a new set of payment rates under the PFS that reflect the relative resource costs of furnishing the technical component of items and services furnished in nonexcepted off campus PBDs. Although we believe that our site-specific HCPCS-level rates reflect the best available estimate of the amount that would have been paid for the service in the office setting under the PFS for practice expenses not associated with the professional component of the service, for the majority of HCPCS codes there is no established methodology for separately valuing the resource costs incurred by a provider while furnishing a service from those incurred exclusively by the facility in which the service is furnished. We continue to explore alternatives to our current estimates that would better reflect the TC of services furnished in nonexcepted off campus PBDs. We are broadly interested in stakeholder feedback and recommendations for ways in which CMS can improve pricing and transparency with regard to the differences in the payment rates across sites of service.

We expect that our continued analyses of claims data and our ongoing exploration of systems changes that are needed to allow nonexcepted off campus PBDs to bill directly for the TC portion of nonexcepted items and services may lead us to consider a different approach for implementing section 603 of the Bipartisan Budget Act of 2015. On the whole, however, we believe that the proposed PFS Relativity Adjuster for CY 2019 of 40 percent would advance the effort to equalize payment rates in the aggregate between physician offices and nonexcepted off-campus PBDs. Maintaining our policy of applying an overall scaling factor to OPPTS payments allows hospitals to continue billing through a facility claim form and permits continued use of the packaging rules and cost report-based relative payment rate determinations for nonexcepted services.

H. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has

also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010 and CY 2015. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.E. of this proposed rule. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period, we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule, the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period, we reviewed the comments received during the 60-day public comment period following release of the

CY 2016 PFS final rule with comment period, and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values. For CY 2017, we did not identify any new codes that described such wholly new services. Therefore, we did not establish any code values on an interim final basis.

For CY 2018, we generally proposed the RUC-recommended work RVUs for new, revised, and potentially misvalued codes. We proposed these values based on our understanding that the RUC generally considers the kinds of concerns we historically raised regarding appropriate valuation of work RVUs. However, during our review of these recommended values, we identified some concerns similar to those we recognized in prior years. Given the relative nature of the PFS and our obligation to ensure that the RVUs reflect relative resource use, we included descriptions of potential alternative approaches we might have taken in developing work RVUs that differed from the RUC-recommended values. We sought comment on both the RUC-recommended values, as well as the alternatives considered. Several commenters generally supported the proposed use of the RUC-recommended work RVUs, without refinement. Other commenters expressed concern about the effect of the misvalued code reviews on particular specialties and settings and disappointment with our proposed approach for valuing codes for CY 2018. A detailed summary of the comments and our responses can be found in the CY 2018 PFS final rule (82 FR 53033–53035).

We clarified in response to commenters that we are not relinquishing our obligation to independently establish appropriate RVUs for services paid under the PFS. We will continue to thoroughly review and consider information we receive from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS

and the federal government as part of our process for establishing valuations. While generally proposing the RUC-recommended work RVUs for new, revised, and potentially misvalued codes was our approach for CY 2018, we note that we also included alternative values where we believed there was a possible opportunity for increased precision. We also clarified that as part of our obligation to establish RVUs for the PFS, we annually make an independent assessment of the available recommendations, supporting documentation, and other available information from the RUC and other commenters to determine the appropriate valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we propose those values as recommended. Additionally, we will continue to engage with stakeholders, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conducted a review that included the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally included, but had not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assessed the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar

codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we used in the building block approach may have included preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We used the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. The statute specifically defines the work component as the resources in time and intensity required in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refined the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where

a service is typically furnished to a beneficiary on the same day as an evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believed that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjusted the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we removed 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also removed a work RVU of 0.09 (4 minutes \times 0.0224 IWPUT) if we did not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist we also include a summary of stakeholder reactions to our approach. We note that many commenters and stakeholders have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY

2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes used the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believed that such changes in time were already accounted for in the RUC's recommendation, then we did not make such adjustments. Likewise, we did not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We used the ratios to identify potential work RVUs and considered these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we have believed that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure

has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several stakeholders, including the RUC, have expressed general objections to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other stakeholders have also expressed general concerns with CMS refinements to RUC recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277) we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule, we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes is one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommended work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

We look forward to continuing to engage with stakeholders and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes, and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to section II.H.4 of this proposed rule for a detailed discussion of the proposed valuation, and alternative valuation considered for specific codes. Table 13 contains a list of codes for which we propose work RVUs; this includes all codes for which we received RUC recommendations by February 10, 2018. The proposed work RVUs, work time and other payment information for all proposed CY 2019 payable codes are available on the CMS website under downloads for the CY 2019 PFS proposed rule. Table 13 also contains

the CPT code descriptors for all proposed, new, revised, and potentially misvalued codes discussed in this section.

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 14 details our refinements of the RUC's direct PE recommendations at the code-specific level. In this proposed rule, we address several refinements that are common across codes, and refinements to particular codes are addressed in the portions of this section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is \$0.30 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the

PE RVU, as well as the impact on the indirect allocator for the average service. We also note that nearly half of the refinements listed in Table 14 result in changes under the \$0.30 threshold and are unlikely to result in a change to the RVUs.

We also note that the proposed direct PE inputs for CY 2019 are displayed in the CY 2019 direct PE input database, available on the CMS website under the downloads for the CY 2019 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>. The inputs displayed there have been used in developing the proposed CY 2019 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to

portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question would be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the "PE worksheets." For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice

clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this proposed rule for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. Some recommendations, however, include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2019, we received invoices for several new supply and equipment items. Tables 15 and 16 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this proposed rule, we encourage stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage stakeholders to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database during the 60-day public comment period for this proposed rule. We expect that invoices received outside of the public comment period would be submitted by February 10th of the following year for consideration in future rulemaking, similar to our new process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 15 and 16 also

include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we included the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the proposed PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our proposed inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address proposed code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the public use files for the PFS proposed and final rules for each year display both the services subject to the MPPR lists on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services. We also include a list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap for the upcoming calendar year. The public use files for CY 2019 are available on the CMS website under downloads for the CY 2019 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>. For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261–74263). For more information regarding the history of the OPPS cap, we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659–69662).

4. Proposed Valuation of Specific Codes for CY 2019

(1) Fine Needle Aspiration (CPT Codes 10021, 10X11, 10X12, 10X13, 10X14, 10X15, 10X16, 10X17, 10X18, 10X19, 76492, 77002 and 77021)

CPT code 10021 was identified as part of the OPPS cap payment proposal in CY 2014 (78 FR 74246–74248), and it was reviewed by the RUC for direct PE inputs only as part of the CY 2016 rule cycle. Afterwards, CPT codes 10021 and 10022 were referred to the CPT Editorial Panel to consider adding additional clarifying language to the code descriptors and to include bundled imaging guidance due to the fact that imaging had become typical with these services. In June 2017, the CPT Editorial Panel deleted CPT code 10022, revised CPT code 10021, and created nine new codes to describe fine needle aspiration procedures with and without imaging guidance. These ten codes were surveyed and reviewed for the October 2017 and January 2018 RUC meetings. Several imaging services were also reviewed along with the rest of the code family, although only CPT code 77021 was subject to a new survey.

For CY 2019, we are proposing the RUC-recommended work RVU for seven of the ten codes in this family. Specifically, we are proposing a work RVU of 0.80 for CPT code 10X11 (Fine needle aspiration biopsy; without

imaging guidance; each additional lesion), a work RVU of 1.00 for CPT code 10X13 (Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion), a work RVU of 1.81 for CPT code 10X14 (Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion), a work RVU of 1.18 for CPT code 10X15 (Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion), and a work RVU of 1.65 for CPT code 10X17 (Fine needle aspiration biopsy, including CT guidance; each additional lesion). We are also proposing to assign the recommended contractor-priced status to CPT codes 10X18 (Fine needle aspiration biopsy, including MR guidance; first lesion) and 10X19 (Fine needle aspiration biopsy, including MR guidance; each additional lesion) due to low utilization until these services are more widely utilized. In addition, we are proposing the recommended work RVU of 1.50 for CPT code 77021 (Magnetic resonance guidance for needle placement (*e.g.*, for biopsy, fine needle aspiration biopsy, injection, or placement of localization device) radiological supervision and interpretation), as well as proposing to reaffirm the current work RVUs of 0.67 for CPT code 76942 (Ultrasonic guidance for needle placement (*e.g.*, biopsy, fine needle aspiration biopsy, injection, localization device), imaging supervision and interpretation) and 0.54 for 77002 (Fluoroscopic guidance for needle placement (*e.g.*, biopsy, fine needle aspiration biopsy, injection, localization device)).

We disagree with the RUC-recommended work RVU of 1.20 for CPT code 10021 (Fine needle aspiration biopsy; without imaging guidance; first lesion) and are proposing a work RVU of 1.03 based on a direct crosswalk to CPT code 36440 (Push transfusion, blood, 2 years or younger). CPT code 36440 is a recently reviewed code with the same intraservice time of 15 minutes and 2 additional minutes of total time. In reviewing CPT code 10021, we noted that the recommended intraservice time is decreasing from 17 minutes to 15 minutes (12 percent reduction), and the recommended total time is decreasing from 48 minutes to 33 minutes (32 percent reduction); however, the RUC-recommended work RVU is only decreasing from 1.27 to 1.20, which is a reduction of just over 5 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two

components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 10021, we believe that it would be more accurate to propose a work RVU of 1.03 based on a crosswalk to CPT code 36440 to account for these decreases in the surveyed work time.

We disagree with the RUC-recommended work RVU of 1.63 for CPT code 10X12 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion) and are proposing a work RVU of 1.46. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 10021 and 10X12 is equivalent to the recommended interval of 0.43 RVUs. Therefore, we are proposing a work RVU of 1.46 for CPT code 10X12, based on the recommended interval of 0.43 additional RVUs above our proposed work RVU of 1.03 for CPT code 10021. The proposed increment of 0.43 RVUs above CPT code 10021 is also based on the use of two crosswalk codes: CPT code 99225 (Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of 3 key components); and CPT code 99232 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of 3 key components). Both of these codes have the same intraservice time and 1 additional minute of total time as compared with CPT code 10X12, and both crosswalk codes share a work RVU of 1.39.

We disagree with the RUC-recommended work RVU of 2.43 for CPT code 10X16 (Fine needle aspiration biopsy, including CT guidance; first lesion) and we are proposing a work RVU of 2.26. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 10021 and 10X16 is equivalent to the recommended interval of 1.23 RVUs. Therefore, we are proposing a work RVU of 2.26 for CPT code 10X16, based on the recommended interval of 1.23 additional RVUs above our proposed work RVU of 1.03 for CPT code 10021. The proposed use of the recommended increment from CPT code 10021 is also based on the use of a crosswalk to CPT code 74263 (Computed tomographic (CT) colonography, screening, including image postprocessing), another CT procedure with 38 minutes of intraservice time and 50 minutes of total time at a work RVU of 2.28.

We note that the recommended work pool is increasing by approximately 20 percent for the Fine Needle Aspiration

family as a whole, while the recommended work time pool for the same codes is only increasing by about 2 percent. Since time is defined as one of the two components of work, we believe that this indicates a discrepancy in the recommended work values. We do not believe that the recoding of the services in this family has resulted in an increase in their intensity, only a change in the way in which they will be reported, and therefore, we do not believe that it would serve the interests of relativity to propose the recommended work values for all of the codes in this family. We believe that, generally speaking, the recoding of a family of services should maintain the same total work pool, as the services themselves are not changing, only the coding structure under which they are being reported. We also note that through the bundling of some of these frequently reported services, it is reasonable to expect that the new coding system will achieve savings via elimination of duplicative assumptions of the resources involved in furnishing particular services. For example, a practitioner would not be carrying out the full preservice work twice for CPT codes 10022 and 76942, but preservice times were assigned to both of the codes under the old coding. We believe the new coding assigns more accurate work times and thus reflects efficiencies in resource costs that existed regardless of how the services were previously reported.

For the direct PE inputs, we are proposing to refine the clinical labor time for the "Prepare room, equipment and supplies" (CA013) activity to 3 minutes and to refine the clinical labor time for the "Confirm order, protocol exam" (CA014) activity to 0 minutes for CPT code 77021. This code did not previously have clinical labor time assigned for the "Confirm order, protocol exam" clinical labor task, and we do not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets. We also note that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(2) Biopsy of Nail (CPT Code 11755)

CPT code 11755 (Biopsy of nail unit (*e.g.*, plate, bed, matrix, hyponychium, proximal and lateral nail folds) (separate procedure)) was identified as potentially

misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, the HCPAC recommended a work RVU of 1.25 based on the survey median value.

We disagree with the recommended value and are proposing a work RVU of 1.08 for CPT code 11755 based on the survey 25th percentile value. We note that the recommended intraservice time for CPT code 11755 is decreasing from 25 minutes to 15 minutes (40 percent reduction), and the recommended total time for CPT code 11755 is decreasing from 55 minutes to 39 minutes (29 percent reduction); however, the recommended work RVU is only decreasing from 1.31 to 1.25, which is a reduction of less than 5 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 11755, we believe that it would be more accurate to propose the survey 25th percentile work RVU than the survey median to account for these decreases in the surveyed work time.

The proposed work RVU of 1.08 is also based on a crosswalk to CPT code 11042 (Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less), which has a work RVU of 1.01, the same intraservice time of 15 minutes, and a similar total time of 36 minutes. We also note that, generally speaking, working with extremities like nails tends to be less intensive in clinical terms than other services, especially as compared to surgical procedures. We believe that this further supports our proposal of a work RVU of 1.08 for CPT code 11755.

We are proposing to refine the equipment times in accordance with our standard equipment time formulas.

(3) Skin Biopsy (CPT Codes 11X02, 11X03, 11X04, 11X05, 11X06, and 11X07)

In CY 2016, CPT codes 11100 (Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; single lesion) and 11101 (Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; each separate/additional lesion) were identified as

potentially misvalued using a high expenditure services screen across specialties with Medicare allowed charges of \$10 million or more. Prior to the January 2016 RUC meeting, the specialty society notified the RUC that its survey data displayed a bimodal distribution of responses with more outliers than usual. The RUC referred CPT codes 11100 and 11101 to the CPT Editorial Panel. In February 2017, the CPT Editorial Panel deleted these two codes and created six new codes for primary and additional biopsy based on the thickness of the sample and the technique utilized.

For CY 2019, we are proposing the RUC-recommended work RVUs for five of the six codes in the family. We are proposing a work RVU of 0.66 for CPT code 11X02 (Tangential biopsy of skin, (e.g., shave, scoop, saucerize, curette), single lesion), a work RVU of 0.83 for CPT code 11X04 (Punch biopsy of skin, (including simple closure when performed), single lesion), a work RVU of 0.45 for CPT code 11X05 (Punch biopsy of skin, (including simple closure when performed), each separate/additional lesion), a work RVU of 1.01 for CPT code 11X06 (Incisional biopsy of skin (e.g., wedge), (including simple closure when performed), single lesion), and a work RVU of 0.54 for CPT code 11X07 (Incisional biopsy of skin (e.g., wedge), (including simple closure when performed), each separate/additional lesion).

For CPT code 11X03 (Tangential biopsy of skin, (e.g., shave, scoop, saucerize, curette), each separate/additional lesion), we disagree with the RUC-recommended work RVU of 0.38 and are proposing a work RVU of 0.29. When we compared the RUC-recommended work RVU of 0.38 to other add-on codes in the RUC database, we found that CPT code 11X03 would have the second-highest work RVU for any code with 7 minutes or less of total time, with the recommended work RVU noticeably higher than other related add-on codes, and we did not agree that the tangential biopsy service being performed should have an anomalously high work value in comparison to other similar add-on codes. Our proposed work RVU of 0.29 is based on a crosswalk to CPT code 11201 (Removal of skin tags, multiple fibrocuteaneous tags, any area; each additional 10 lesions, or part thereof), a clinically related add-on procedure with 5 minutes of intraservice and total time as opposed to the surveyed 6 minutes for CPT code 11X03. We also noted that the intraservice time ratio between CPT code 11X03 and the recommended reference code, CPT code 11732

(Avulsion of nail plate, partial or complete, simple; each additional nail plate), was 75 percent (6 minutes divided by 8 minutes). This 75 percent ratio when applied to the work RVU of CPT code 11732 also produced a work RVU of 0.29 ($0.38 \times 0.75 = 0.29$). Finally, we are also supporting the proposed work RVU through a crosswalk to CPT code 33508 (Endoscopy, surgical, including video-assisted harvest of vein(s) for coronary artery bypass procedure), which has a higher intraservice time of 10 minutes but a similar work RVU of 0.31. We believe that our proposed work RVU of 0.29 for CPT code 11X03 better serves the interests of relativity, as well as better fitting with the other recommended work RVUs within this family of codes.

For the direct PE inputs, we are proposing to remove the 2 minutes of clinical labor time for the "Review home care instructions, coordinate visits/prescriptions" (CA035) activity for CPT codes 11X02, 11X04, and 11X06. These codes are typically billed with a same day E/M service, and we believe that it would be duplicative to assign clinical labor time for reviewing home care instructions given that this task would typically be done during the same day E/M service. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

We are proposing to refine the quantity of the "gown, staff, impervious" (SB024) and the "mask, surgical, with face shield" (SB034) supplies from 2 to 1 for CPT codes 11X02, 11X04, and 11X06. We are proposing to remove one gown and one surgical mask from these codes as duplicative since these supplies are also included within the surgical instrument cleaning pack (SA043). We are also proposing to remove all of the supplies in the three add-on procedures (CPT codes 11X03, 11X05, and 11X07) that were not contained in the previous add-on procedure for this family, CPT code 11101. We do not believe that the use of these supplies would be typical for the "each additional lesion" add-on codes, as these supplies are all included in the base codes and are not currently utilized in CPT code 11101. We note that the recommended direct PE costs for the three new add-on codes represent an increase of approximately 500 percent from the direct PE costs for CPT code 11101, and believe that this is largely due to the addition of these new supplies.

(4) Injection Tendon Origin-Insertion (CPT Code 20551)

CPT code 20551 (Injection(s); single tendon origin/insertion) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we are proposing the RUC-recommended work RVU of 0.75 for CPT code 20551.

We are proposing to maintain the current work RVU for many of the CPT codes identified as potentially misvalued on the screen of 0-day global services reported with an E/M visit 50 percent of the time or more. We note that regardless of the proposed work valuations for individual codes, which may or may not retain the same work RVU, we continue to have reservations about the valuation of 0-day global services that are typically billed with a separate E/M service with the use of Modifier 25 (indicating that a significant and separately identifiable E/M service was provided on the same day). As we stated in the CY 2017 PFS final rule (81 FR 80204), we continue to believe that the routine billing of separate E/M services in conjunction with a particular code may indicate a possible problem with the valuation of the code bundle, which is intended to include all the routine care associated with the service. We will continue to consider additional ways to address the appropriate valuation for these services.

For the direct PE inputs, we are proposing to remove the clinical labor time for the "Provide education/obtain consent" (CA011) and the "Review home care instructions, coordinate visits/prescriptions" (CA035) activities for CPT code 20551. This code is typically billed with a same day E/M service, and we believe that it would be duplicative to assign clinical labor time for obtaining consent or reviewing home care instructions given that these tasks would typically be done during the same day E/M service. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(5) Structural Allograft (CPT Codes 209X3, 209X4, and 209X5)

In February 2017, the CPT Editorial Panel created three new codes to describe allografts. These codes were designated as add-on codes and revised to more accurately describe the structural allograft procedures they represent. For CY 2019, we are

proposing the RUC-recommended work RVUs for all three codes. We are proposing a work RVU of 13.01 for CPT code 209X3 (Allograft, includes templating, cutting, placement and internal fixation when performed; osteoarticular, including articular surface and contiguous bone), a work RVU of 11.94 for CPT code 209X4 (Allograft, includes templating, cutting, placement and internal fixation when performed; hemicortical intercalary, partial (*i.e.*, hemicylindrical)), and a work RVU of 13.00 for CPT code 209X5 (Allograft, includes templating, cutting, placement and internal fixation when performed; intercalary, complete (*i.e.*, cylindrical)).

These three new codes are all facility-only procedures with no recommended direct PE inputs.

(6) Knee Arthrography Injection (CPT Code 27X69)

CPT code 27370 (Injection of contrast for knee arthrography) repeatedly appeared on high volume growth screens between 2008 and 2016, and the RUC expressed concern that the high volume growth for this procedure was likely due to its being reported incorrectly as arthrocentesis or aspiration. In June 2017, the CPT Editorial Panel deleted CPT code 27370 and replaced it with a new code, 27X69, to report injection procedure for knee arthrography or enhanced CT/MRI knee arthrography.

The RUC recommended a work RVU for CPT code 27X69 of 0.96, which is identical to the work RVU for CPT code 27370 (Injection of contrast for knee arthrography). The RUC's recommendation is based on key reference service, CPT code 23350 (Injection procedure for shoulder arthrography or enhanced CT/MRI shoulder arthrography), with identical intraservice time (15 minutes) and total time (28 minutes) as the new CPT code and a work RVU of 1.00. The RUC notes that its recommendation is lower than the 25th percentile from the survey results, but that the work described by the service should be valued identically with the CPT code being replaced. We disagree with the RUC's recommended work RVU for CPT code 27X69. Both the total (28 minutes) and intraservice (15 minutes) times for the new CPT code are considerably lower than the deleted CPT code 27370. Based on the reduced times and the projected work RVU from the reverse building block methodology (0.60 work RVUs), we believe this CPT code should be valued at 0.77 work RVUs, supported by a crosswalk to CPT code 29075 (Application, cast; elbow to finger (short arm)), with total time of 27

minutes and intraservice time of 15 minutes. Therefore, we are proposing a work RVU of 0.77 for CPT code 27X69.

For the direct PE inputs, we are proposing to refine the clinical labor time for the "Prepare room, equipment and supplies" (CA013) activity to 3 minutes and to refine the clinical labor time for the "Confirm order, protocol exam" (CA014) activity to 0 minutes. The predecessor code for 27X69, CPT code 27370, did not previously have clinical labor time assigned for the "Confirm order, protocol exam" clinical labor task, and we do not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets. We also note that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished.

We are proposing to remove the clinical labor time for the "Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue" (CA032) activity. CPT code 27X69 does not include a PACS workstation among the recommended equipment, and the predecessor code 27370 did not previously include time for this clinical labor activity. We believe that data entry activities such as this task would be classified as indirect PE, as they are considered administrative activities and are not individually allocable to a particular patient for a particular service. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(7) Application of Long Arm Splint (CPT Code 29105)

CPT code 29105 (Application of long arm splint (shoulder to hand)) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we are proposing the RUC-recommended work RVU of 0.80 for CPT code 29105.

For the direct PE inputs, we are proposing to refine the equipment times in accordance with our standard equipment time formulas.

(8) Strapping Lower Extremity (CPT Codes 29540 and 29550)

CPT codes 29540 (Strapping; ankle and/or foot) and 29550 (Strapping; toes) were identified as potentially misvalued

on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we are proposing the HCPAC-recommended work RVU of 0.39 for CPT code 29540 and the HCPAC-recommended work RVU of 0.25 for CPT code 29550.

For the direct PE inputs, we are proposing to refine the clinical labor time for the “Provide education/obtain consent” (CA011) activity from 3 minutes to 2 minutes for both codes, as this is the standard clinical labor time assigned for patient education and consent. We are also proposing to remove the 2 minutes of clinical labor time for the “Review home care instructions, coordinate visits/prescriptions” (CA035) activity for both codes. CPT codes 29540 and 29550 are both typically billed with a same day E/M service, and we believe that it would be duplicative to assign clinical labor time for reviewing home care instructions given that this task would typically be done during the same day E/M service. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(9) Bronchoscopy (CPT Codes 31623 and 31624)

CPT code 31623 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with brushing or protected brushings) was identified on a high growth screen of services with total Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2009 through 2014. CPT code 31624 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial alveolar lavage) was also included for review as part of the same family of codes. For CY 2019, we are proposing the RUC-recommended work RVU of 2.63 for CPT codes 31623 and 31624.

For the direct PE inputs, we are proposing to refine the clinical labor time for the “Complete post-procedure diagnostic forms, lab and x-ray requisitions” (CA027) activity from 4 minutes to 2 minutes for CPT codes 31623 and 31624. Two minutes is the standard time, as well as the current time for this clinical labor activity, and we have no reason to believe that the time to perform this task has increased since the codes were last reviewed. We did not receive any explanation in the recommendations as to why the time for

this activity would be doubling over the current values. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(10) Pulmonary Wireless Pressure Sensor Services (CPT Codes 332X0 and 93XX1)

In September 2017, the CPT Editorial Panel created a code to describe pulmonary wireless sensor implantation and another code for remote care management of patients with an implantable, wireless pulmonary artery pressure sensor monitor. For CY 2019, we are proposing the RUC-recommended work RVU of 6.00 for CPT code 332X0 (Transcatheter implantation of wireless pulmonary artery pressure sensor for long term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed), and the RUC-recommended work RVU of 0.70 for CPT code 93XX1 (Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional).

We are not proposing any direct PE refinements for this code family.

(11) Cardiac Event Recorder Procedures (CPT Codes 332X5 and 332X6)

In February 2017, the CPT Editorial Panel created two new codes replacing cardiac event recorder codes to reflect new technology. For CY 2019, we are proposing the RUC-recommended work RVU of 1.53 for CPT code 332X5 (Insertion, subcutaneous cardiac rhythm monitor, including programming) and the RUC-recommended work RVU of 1.50 for CPT code 332X6 (Removal, subcutaneous cardiac rhythm monitor).

We are not proposing any direct PE refinements for this code family.

(12) Aortoventriculoplasty With Pulmonary Autograft (CPT Code 335X1)

In September 2017, the CPT Editorial Panel created one new code to combine the efforts of aortic valve and root replacement with subvalvular left ventricular outflow tract enlargement to allow for an unobstructed left ventricular outflow tract.

For CY 2019, we are proposing the RUC-recommended work RVU of 64.00 for CPT code 335X1 (Replacement, aortic valve; by translocation of

autologous pulmonary valve and transventricular aortic annulus enlargement of the left ventricular outflow tract with valved conduit replacement of pulmonary valve (Ross-Konno procedure)). When this code is re-reviewed in a few years as part of the new technology screen, we look forward to receiving new recommendations on the whole family, including the related Ross and Konno procedures (CPT codes 33413 and 33412 respectively) that were used as references for CPT code 335X1.

For the direct PE inputs, we are proposing to refine the preservice clinical labor times to match our standards for 90-day global procedures. We are proposing to refine the clinical labor time for the “Coordinate pre-surgery services (including test results)” (CA002) activity from 25 minutes to 20 minutes, to refine the clinical labor time for the “Schedule space and equipment in facility” (CA003) activity from 12 minutes to 8 minutes, and to refine the clinical labor time for the “Provide pre-service education/obtain consent” (CA004) activity from 26 minutes to 20 minutes. We are also proposing to add 15 minutes of clinical labor time for the “Perform regulatory mandated quality assurance activity (pre-service)” (CA008) activity. We agree with the recommendation that the total preservice clinical labor time for CPT code 335X1 is unchanged from the two reference codes at 75 minutes. However, we believe that the clinical labor associated with additional coordination between multiple specialties prior to patient arrival is more accurately described through the use of the CA008 activity code than by distributing this 15 minutes amongst the other preservice clinical labor activities. We previously established standard preservice times for 90-day global procedures, and did not want to propose clinical labor times above those standards for CPT code 335X1. We also note that there is no effect on the total clinical labor direct costs in this situation, since the same 15 minutes of preservice clinical labor time is still being furnished.

(13) Hemi-Aortic Arch Replacement (CPT Code 33X01)

At the September 2017 CPT Editorial Panel meeting, the Panel created one new add-on code to report hemi-aortic arch graft replacement. For CY 2019, we are proposing the RUC-recommended work RVU of 19.74 for CPT code 33X01 (Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion). CPT code

33X01 is a facility-only procedure with no recommended direct PE inputs.

(14) Leadless Pacemaker Procedures (CPT Codes 33X05 and 33X06)

At the September 2017 CPT Editorial Panel meeting, the Panel replaced the five leadless pacemaker services Category III codes with the addition of two new CPT codes to report transcatheter leadless pacemaker procedures and revised five codes to include evaluation and interrogation services of leadless pacemaker systems.

For CPT code 33X05 (Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed), we disagree with the recommended work RVU of 8.77 and we are proposing a work RVU of 7.80 based on a direct crosswalk to one of the top reference codes selected by the RUC survey participants, CPT code 33207 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular). This code has the same 60 minutes of intraservice time as CPT code 33X05 and an additional 61 minutes of total time at a work RVU of 7.80. In our review of CPT code 33X05, we noted that this reference code had an additional inpatient hospital visit of CPT code 99232 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of 3 key components) and a full instead of a half discharge visit of CPT code 99238 (Hospital discharge day management; 30 minutes or less) included in its 90-day global period. The combined work RVU of these two visits would be equal to 2.03. However, the recommended work RVU for CPT code 33X05 was 0.97 work RVUs higher than CPT code 33207, despite having fewer of these visits and significantly less surveyed total time. While we acknowledge that CPT code 33X05 is a more intense procedure than CPT code 33207, we do not believe that it should be valued almost a full RVU higher than the reference code given the fewer visits in the global period and the lower surveyed work time.

Therefore, we are proposing to crosswalk CPT code 33X05 to CPT code 33207 at the same work RVU of 7.80. The proposed work RVU is also supported through a reference crosswalk to CPT code 38542 (Dissection, deep jugular node(s)), which has 60 minutes of intraservice time, 198 minutes of total time, and a work RVU of 7.95. We believe that our proposed work RVU of

7.80 is a more accurate valuation for CPT code 33X05, while still recognizing the greater intensity of this procedure in comparison to its reference code.

For CPT code 33X06 (Transcatheter removal of permanent leadless pacemaker, right ventricular), we disagree with the RUC-recommended work RVU of 9.56 and we are proposing a work RVU of 8.59. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 33X05 and 33X06 is equivalent to the recommended interval of 0.79 RVUs. Therefore, we are proposing a work RVU of 8.59 for CPT code 33X06, based on the recommended interval of 0.79 additional RVUs above our proposed work RVU of 7.80 for CPT code 33X05. We also note that our proposed work RVU for CPT code 33X06 situates it approximately halfway between the two reference codes from the survey, with CPT code 33270 (Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed) having an intraservice time of 90 minutes and a work RVU of 9.10, and CPT code 33207 having an intraservice time of 60 minutes and a work RVU of 7.80. CPT code 33X06 has a surveyed intraservice time of 75 minutes and nearly splits the difference between them at our proposed work RVU of 8.59.

We are not proposing any direct PE refinements for this code family.

(15) PICC Line Procedures (CPT Codes 36568, 36569, 36X72, 36X73, and 36584)

In CY 2016, CPT code 36569 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; age 5 years or older) was identified as potentially misvalued using a high expenditure services screen across specialties with Medicare allowed charges of \$10 million or more. CPT code 36569 is typically reported with CPT codes 76937 (Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting) and 77001 (Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal) and was

referred to the CPT Editorial Panel to have the two common imaging codes bundled into the code. In September 2017, the CPT Editorial Panel revised CPT codes 36568 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump; younger than 5 years of age), 36569 and 36584 (Replacement, complete, of a peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, through same venous access, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the replacement) and created two new CPT codes to specify the insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion.

For CY 2019, we are proposing the RUC-recommended work RVU for two of the CPT codes in the family. We are proposing the RUC-recommended work RVU of 2.11 for CPT code 36568 and the RUC-recommended work RVU of 1.90 for CPT code 36569.

For CPT code 36X72 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; younger than 5 years of age), we disagree with the RUC-recommended work RVU of 2.00 and are proposing a work RVU of 1.82 based on a direct crosswalk to CPT code 50435 (Exchange nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation). CPT code 50435 is a recently reviewed code that also includes radiological supervision and interpretation with similar intraservice and total time values. In our review of CPT code 36X72, we were concerned about the possibility that the recommended work RVU of 2.00 could create a rank order anomaly in terms of intensity with the other codes in the family. We noted that the recommended intraservice time for CPT code 36X72 as compared to CPT code 36568, the most similar code in the family, is decreasing from 38 minutes to 22 minutes (42 percent), and the recommended total time is decreasing from 71 minutes to 51 minutes (38

percent); however, the recommended work RVU is only decreasing from 2.11 to 2.00, which is a reduction of just over 5 percent. We also noted that CPT code 36X72 has a lower recommended intraservice time and total time as compared to CPT code 36569, yet has a higher recommended work RVU. Although we do not imply that the decreases in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs.

In the case of CPT code 36X72, we believe that it would be more accurate to propose a work RVU of 1.82 based on a crosswalk to CPT code 50435 to better fit with the recommended work RVUs for CPT codes 36568 and 36569. The proposed work valuation is also based on the use of three additional crosswalk codes: CPT code 32554 (Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance), CPT code 43198 (Esophagoscopy, flexible, transnasal; with biopsy, single or multiple), and CPT code 64644 (Chemodenervation of one extremity; 5 or more muscles). All of these codes were recently reviewed with similar intensity, intraservice time, and total time values, and all three of them also share a work RVU of 1.82.

For CPT code 36X73 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older), we disagree with the RUC-recommended work RVU of 1.90 and are proposing a work RVU of 1.70 based on maintaining the current work RVU of CPT code 36569. In our review of CPT code 36X73, we were again concerned about the possibility that the recommended work RVU of 1.90 could create a rank order anomaly in terms of intensity with the other codes in the family. We noted that the recommended intraservice time for CPT code 36X73 as compared to CPT code 36569, the most similar code in the family, is decreasing from 27 minutes to 15 minutes (45 percent), and the recommended total time is decreasing from 60 minutes to 40 minutes (33 percent); however, the RUC-recommended work RVU is exactly the same for these two codes at 1.90. Although we do not imply that the decreases in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work

RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs.

In the case of CPT code 36X73, we believe that it would be more accurate to propose a work RVU of 1.70 based on maintaining the current work RVU of CPT code 36569. These two CPT codes describe the same procedure done with (CPT code 36X73) and without (CPT code 36569) imaging guidance and radiological supervision and interpretation. Because the inclusion of the imaging described by CPT code 36X73 has now become the typical case for this service, we believe that it is more accurate to maintain the current work RVU of 1.70 as opposed to increasing the work RVU to 1.90, especially considering that the new surveyed work time for CPT code 36X73 is lower than the current work time for CPT code 36569. The proposed work RVU of 1.70 is also based on a crosswalk to CPT code 36556 (Insertion of non-tunneled centrally inserted central venous catheter; age 5 years or older). This is a recently reviewed code with the same 15 minutes of intraservice time and the same 40 minutes of total time with a work RVU of 1.75.

For CPT code 36584, we disagree with the RUC-recommended work RVU of 1.47 and are proposing a work RVU of 1.20 based on maintaining the current work RVU. We note that the recommended intraservice time for CPT code 36584 is decreasing from 15 minutes to 12 minutes (20 percent reduction), and the recommended total time is decreasing from 45 minutes to 34 minutes (25 percent reduction); however, the recommended work RVU is increasing from 1.20 to 1.47, an increase of approximately 23 percent. Although we do not imply that the decreases in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. We are especially concerned when the recommended work RVU is increasing despite survey results indicating that the work time is decreasing due to a combination of improving technology and greater efficiencies in practice patterns.

In the case of CPT code 36584, we believe that it would be more accurate to propose a work RVU of 1.20 based on maintaining the current work RVU for the code. Because the inclusion of the imaging has now become the typical case for this service, we believe that it

is more accurate to maintain the current work RVU of 1.20 as opposed to increasing the work RVU to 1.47, especially considering that the new surveyed work time for CPT code 36584 is decreasing from the current work time. The proposed work RVU of 1.20 is also based on a crosswalk to CPT code 40490 (Biopsy of lip), which has the same total time of 34 minutes and slightly higher intraservice time at a work RVU of 1.22.

We note that the RUC-recommended work pool is increasing by approximately 68 percent for the PICC Line Procedures family as a whole, while the RUC-recommended work time pool for the same codes is only increasing by about 22 percent. Since time is defined as one of the two components of work, we believe that this indicates a discrepancy in the recommended work values. We do not believe that the recoding of the services in this family has resulted in an increase in their intensity, only a change in the way in which they will be reported, and therefore, we do not believe that it would serve the interests of relativity to propose the RUC-recommended work values for all of the codes in this family. We believe that, generally speaking, the recoding of a family of services should maintain the same total work pool, as the services themselves are not changing, only the coding structure under which they are being reported. We also note that, through the bundling of some of these frequently reported services, it is reasonable to expect that the new coding system will achieve savings via elimination of duplicative assumptions of the resources involved in furnishing particular services. For example, a practitioner would not be carrying out the full preservice work three times for CPT codes 36568, 76937, and 77001, but preservice times were assigned to all of the codes under the old coding. We believe the new coding assigns more accurate work times and thus reflects efficiencies in resource costs that existed but were not reflected in the services as they were previously reported.

For the direct PE inputs, we are proposing to refine the clinical labor time for the "Prepare, set-up and start IV, initial positioning and monitoring of patient" (CA016) activity from 4 minutes to 2 minutes for CPT codes 36X72 and 36X73. We note that the two reference codes for the two new codes, CPT codes 36568 and 36569, currently have 2 minutes assigned for this activity, and CPT code 36584 also has a recommended 2 minutes assigned to this same activity. We do not agree that the patient positioning would take twice

as long for CPT codes 36X72 and 36X73 as compared to the rest of the family, and are therefore refining both of them to the same 2 minutes of clinical labor time. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(16) Biopsy or Excision of Inguinofemoral Node(s) (CPT Code 3853X)

In September 2017, the CPT Editorial Panel created a new code to describe biopsy or excision of inguinofemoral node(s). A parenthetical was added to CPT codes 56630 (Vulvectomy, radical, partial) and 56633 (Vulvectomy, radical, complete) to instruct separate reporting of code 3853X with radical vulvectomy. This service was previously reported with unlisted codes.

CPT code 3853X (Biopsy or excision of lymph node(s); open, inguinofemoral node(s)) is a new CPT code describing a lymph node biopsy without complete lymphadenectomy. The RUC recommended a work RVU of 6.74 for CPT code 3853X, with 223 minutes of total time and 65 minutes of intraservice time. We propose the RUC-recommended work RVU of 6.74 for CPT code 3853X. However, we are concerned that this CPT code is described as having a 10-day global period. The two CPT codes that are often reported together with this code, CPT code 56630 (Vulvectomy, radical, partial) and CPT code 56633 (Vulvectomy, radical, complete), are both 90-day global codes. In addition, CPT code 3853X has a discharge visit and two follow up visits in the global period. This is consistent with the number of postoperative visits typically associated with 90-day global codes. Therefore, we propose to assign a 90-day global indicator for CPT code 3853X rather than the 10-day global time period reflected in the RUC recommendation.

We are not proposing any direct PE refinements for this code family.

(17) Radioactive Tracer (CPT Code 38792)

CPT code 38792 (Injection procedure; radioactive tracer for identification of sentinel node) was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. For CY 2019, we are proposing the RUC-recommended work RVU of 0.65 for CPT code 38792.

For the direct PE inputs, we are proposing to refine the clinical labor

time for the “Prepare room, equipment and supplies” (CA013) activity to 3 minutes and to refine the clinical labor time for the “Confirm order, protocol exam” (CA014) activity to 0 minutes. CPT code 38792, as well as its alternate reference code 78300 (Bone and/or joint imaging; limited area), both did not previously have clinical labor time assigned for the “Confirm order, protocol exam” clinical labor task, and we do not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets. We also note that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(18) Percutaneous Change of G-Tube (CPT Code 43760)

CPT code 43760 (Change of gastrostomy tube, percutaneous, without imaging or endoscopic guidance) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. It was surveyed for the April 2017 RUC meeting and recommendations for work and direct PE inputs were submitted to CMS. However, the RUC also noted that because the data for CPT code 43760 were bimodal, it might be appropriate to consider changes in the CPT descriptors to better differentiate physician work. In September 2017, the CPT Editorial Panel deleted CPT code 43760 and will use two new codes (43X63 and 43X64) that describe replacement of gastrostomy tube, with and without revision of gastrostomy tract, respectively. (See below.) Therefore, we are not proposing work or direct PE values for CPT code 43760.

(19) Gastrostomy Tube Replacement (CPT Codes 43X63 and 43X64)

In September 2017, the CPT Editorial Panel created two new codes that describe replacement of gastrostomy tube, with and without revision of gastrostomy tract, respectively. These two new codes were surveyed for the January 2018 RUC meeting and recommendations for work and direct PE inputs were submitted to CMS.

We are proposing a work RVU of 0.75 for CPT code 43X63 (Replacement of

gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; not requiring revision of gastrostomy tract.) and a work RVU of 1.41 for CPT code 43X64 (Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract.), consistent with the RUC’s recommendations for these new CPT codes.

For the direct PE inputs, we are proposing to refine the equipment times in accordance with our standard equipment time formulas.

(20) Diagnostic Proctosigmoidoscopy—Rigid (CPT Code 45300)

CPT code 45300 (Proctosigmoidoscopy, rigid; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we are proposing the RUC-recommended work RVU of 0.80 for CPT code 45300.

For the direct PE inputs, we are proposing to refine the equipment times in accordance with our standard equipment time formulas.

(21) Hemorrhoid Injection (CPT Code 46500)

CPT code 46500 (Injection of sclerosing solution, hemorrhoids) was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes.

For CPT code 46500, we disagree with the RUC-recommended work RVU of 2.00 and we are proposing a work RVU of 1.74 based on a direct crosswalk to CPT code 68811 (Probing of nasolacrimal duct, with or without irrigation; requiring general anesthesia). This is another recently-reviewed 10-day global code with the same 10 minutes of intraservice time and slightly higher total time. When CPT code 46500 was previously reviewed as described in the CY 2016 PFS final rule with comment period (80 FR 70963), we finalized a proposal to reduce the work RVU from 1.69 to 1.42, which reduced the work RVU by the same ratio as the

reduction in the total work time. In light of the additional evidence provided by this new survey, we agree that the work RVU should be increased from the current value of 1.42. However, we believe that our proposed work RVU of 1.74 based on a crosswalk to CPT code 68811 is more accurate than the RUC-recommended work RVU of 2.00.

In the most recent survey of CPT code 46500, the intraservice work time remained unchanged at 10 minutes while the total time increased by only 2 minutes, increasing from 59 minutes to 61 minutes (3 percent). However, the RUC-recommended work RVU is increasing from 1.42 to 2.00, an increase of 41 percent, and also an increase of 19 percent over the historic value of 1.69 for CPT code 46500. Although we do not imply that the increase in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, minimal increases in surveyed work time typically should not be reflected in disproportionately large increases to work RVUs. In the case of CPT code 46500, we believe that our crosswalk to CPT code 68811 at a work RVU of 1.74 more accurately maintains relativity with other 10-day global codes on the PFS. We also note that the 3 percent increase in surveyed work time for CPT code 46500 matches a 3 percent increase in the historic work RVU of the code, from 1.69 to 1.74. Therefore, we are proposing a work RVU of 1.74 for CPT code 46500 based on the aforementioned crosswalk.

For the direct PE inputs, we are proposing to remove 10 minutes of clinical labor time for the “Assist physician or other qualified healthcare professional—directly related to physician work time (100%)” (CA018) activity. This clinical labor time is listed twice in the recommendations along with a statement that although the clinical labor has not changed from prior reviews, time for both clinical staff members was inadvertently not included in the previous spreadsheets. We appreciate this notification in the recommendations, and therefore, we are asking for more information about why the clinical labor associated with this additional staff member was left out for previous reviews. We are particularly interested in knowing what activities the additional staff member would be undertaking during the procedure. We are proposing to remove the clinical labor associated with this additional clinical staff member pending the receipt of additional information. We are also proposing to remove 1 impervious staff gown (SB027), 1

surgical mask with face shield (SB034), and 1 pair of shoe covers (SB039) pending more information about the additional clinical staff member.

We are proposing to remove the clinical labor time for the “Review home care instructions, coordinate visits/prescriptions” (CA035) activity. CPT code 46500 is typically billed with a same day E/M service, and we believe that it would be duplicative to assign clinical labor time for reviewing home care instructions given that this task would typically be done during the same day E/M service. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(22) Removal of Intraperitoneal Catheter (CPT Code 49422)

In October 2016, CPT code 49422 (Removal of tunneled intraperitoneal catheter) was identified as a site of service anomaly because Medicare data from 2012–2014 indicated that it was performed less than 50 percent of the time in the inpatient setting, yet included inpatient hospital E/M services within the 10-day global period. The code was resurveyed using a 0-day global period for the April 2017 RUC meeting. For CY 2019, we are proposing the RUC-recommended work RVU of 4.00 for CPT code 49422.

We are not proposing any direct PE refinements for this code family.

(23) Dilation of Urinary Tract (CPT Codes 50X39, 50X40, 52334, and 74485)

In October 2014, the CPT Editorial Panel deleted six codes and created twelve new codes to describe genitourinary catheter procedures and bundle inherent imaging services. In January 2015, the specialty societies indicated that CPT code 50395 (Introduction of guide into renal pelvis and/or ureter with dilation to establish nephrostomy tract, percutaneous), which was identified as part of the family, would be referred to the CPT Editorial Panel to clear up any confusion with overlap in physician work with CPT code 50432 (Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.*, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation). In September 2017, the CPT Editorial Panel deleted CPT code 50395 and created two new codes to report dilation of existing tract, and establishment of new access to the collecting system, including percutaneous, for an endourologic procedure including imaging guidance

(*e.g.*, ultrasound and/or fluoroscopy), all associated radiological supervision and interpretation, as well as post procedure tube placement when performed.

The specialty society surveyed the new CPT code 50X39 (Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (*e.g.*, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, as well as post procedure tube placement, when performed), and the RUC recommended a total time of 70 minutes, intraservice time of 30 minutes, and a work RVU of 3.37. The RUC indicated that its recommended work RVU for this CPT code is identical to the work RVU of the CPT code being deleted, even though imaging guidance CPT code 74485 has now been bundled into the valuation of the CPT code. The RUC provided two key reference CPT codes to support its recommendation: CPT code 50694 (Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.*, ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; new access, without separate nephrostomy catheter) with total time of 111 minutes, intraservice time of 62 minutes, and a work RVU of 5.25; and CPT code 50695 (Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.*, ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; new access, with separate nephrostomy catheter), with total time of 124 minutes and intraservice time of 75 minutes, and a work RVU of 6.80. To further support its recommendation, the RUC also referenced CPT code 52287 (Cystourethroscopy, with injection(s) for chemodenervation of the bladder) with total time of 58 minutes, intraservice time of 21 minutes, and a work RVU of 3.37. We disagree with the RUC that the work RVU for this CPT code should be the same as the CPT code being deleted. Survey respondents indicated that the total time for completing the service described by the new CPT code is nearly 30 minutes less than the existing CPT code, even though imaging guidance was described as part of the procedure. We also note that the reference CPT codes both have substantially higher total and intraservice times than CPT code 50X39. We considered a number of parameters to arrive at our proposed work RVU of 2.78, supported by a

crosswalk to CPT code 31646 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with therapeutic aspiration of tracheobronchial tree, subsequent, same hospital stay). We examined the intraservice time ratio for the new CPT code in relation to the combination of CPT codes that the service represents and found that this would support a work RVU of 2.55. We also calculated the intraservice time ratio for the new CPT code in relation to each of the two reference CPT codes. For the comparison with CPT code 50694, the intraservice time ratio is 2.54, while the comparison with the second reference CPT code 50695 yields an intraservice time ratio of 2.72. We took the highest of these three values, 2.72, and found a corresponding crosswalk that we believe appropriately values the service described by the new CPT code. Therefore, we are proposing a work RVU of 2.78 for CPT code 50X39.

The specialty society also surveyed the new CPT code 50X40 (Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, as well as post procedure tube placement, when performed; including new access into the renal collecting system) and the RUC recommended a total time of 100 minutes, an intraservice time of 60 minutes, and a work RVU of 5.44. The recommended intraservice time of 60 minutes reflects the 75th percentile of survey results, rather than the median survey time, which is typically used for determining the intraservice time for new CPT codes. The RUC justified the use of the higher intraservice time because they believe the time better represents the additional time needed to introduce the guidewire into the renal pelvis and/or ureter, above and beyond the work involved in performing CPT code 50X39. The RUC compared this CPT code to CPT code 52235 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; MEDIUM bladder tumor(s) (2.0 to 5.0 cm)), with total time of 94 minutes, intraservice time of 45 minutes, and a work RVU of 5.44. The RUC also cited, as support, the second key reference CPT code 50694 (Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; new

access, without separate nephrostomy catheter) with total time 111 minutes, intraservice time 62 minutes, and a work RVU of 5.25. We do not agree with the RUC's recommended work RVU because we believe that the intraservice time for this CPT code should reflect the survey median rather than the 75th percentile. There is no indication that the additional work of imaging guidance was systematically excluded by survey respondents when estimating the time needed to furnish the service. Therefore, we are proposing to reduce the intraservice time for CPT code 50X40 from the RUC-recommended 60 minutes to the survey median time of 45 minutes. We note that this is still 15 minutes more than the intraservice time for CPT code 50X39, primarily for the provider to introduce the guidewire into the renal pelvis and/or ureter. We welcome comments about the amount of time needed to furnish this procedure. With the revised intraservice time of 45 minutes and a total time of 85 minutes, we believe that the RUC-recommended work RVU for this CPT code is overstated. When we apply the increment between the RUC-recommended values for between CPT codes 50X39 and 50X40 (2.07 work RVUs) in addition to our proposed work RVU for CPT code 50X39, we estimate that this CPT code is more accurately represented by a work RVU of 4.83. This value is supported by a crosswalk to CPT code 36902 (Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty), which has intraservice time of 40 minutes and total time of 86 minutes. We believe that CPT code 36902 describes a service that is similar to the new CPT code 50X40 and therefore provides a reasonable crosswalk. We are proposing a work RVU of 4.83 for CPT code 50X40.

We are proposing the RUC-recommended work RVU of 3.37 for CPT code 52334 (Cystourethroscopy with insertion of ureteral guide wire through kidney to establish a percutaneous nephrostomy, retrograde)

and the RUC-recommended work RVU of 0.83 for CPT code 74485 (Dilation of ureter(s) or urethra, radiological supervision and interpretation).

For the direct PE inputs, we are proposing to remove the clinical labor time for the "Confirm availability of prior images/studies" (CA006) activity for CPT code 52334. This code does not currently include this clinical labor time, and unlike the two new codes in the family (CPT codes 50X39 and 50X40), CPT code 52234 does not include imaging guidance in its code descriptor. When CPT code 52234 is performed with imaging guidance, it would be billed together with a separate imaging code that already includes clinical labor time for confirming the availability of prior images. As a result, we believe that it would be duplicative to include this clinical labor time in CPT code 52234.

(24) Transurethral Destruction of Prostate Tissue (CPT Codes 53850, 53852, and 538X3)

In September 2017, the CPT Editorial Panel created a new code (CPT code 538X3) to report transurethral destruction of prostate tissue by radiofrequency-generated water vapor thermotherapy. CPT codes 53850 (Transurethral destruction of prostate tissue; by microwave thermotherapy) and 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy) were also included for review as part of the same family of codes.

For CPT code 53850 (Transurethral destruction of prostate tissue; by microwave thermotherapy), the RUC-recommended a work RVU of 5.42, supported by a direct crosswalk to CPT code 33272 (Removal of subcutaneous implantable defibrillator electrode) with a total time of 151 minutes, intraservice time of 45 minutes, and a work RVU of 5.42. The RUC indicated that a work RVU of 5.42 accurately reflects the lowest value of the three CPT codes in this family. We are proposing the work RVU of 5.42 for CPT code 53850, as recommended by the RUC.

The RUC recommended a work RVU of 5.93 for CPT code 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy) and for CPT code 538X3 (Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy). We are proposing the RUC-recommended value of 5.93 for CPT code 53852.

CPT code 538X3 (Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy) is a service reflecting

the use of a new technology, “radiofrequency generated water vapor thermotherapy,” as distinct from CPT code 53852, which describes destruction of tissue by “radiofrequency thermotherapy.” The RUC indicated that this CPT code is the most intense of the three CPT codes in this family, thereby justifying a work RVU identical to that of CPT code 53852 despite lower intraservice and total times. The RUC stated that 15 minutes of post service time is appropriate due to greater occurrence of post-procedure hematuria necessitating a longer monitoring time. However, the post-service monitoring time for this CPT code, 15 minutes, is identical to that for CPT code 53852. We do not agree with the explanation provided by the RUC for recommending a work RVU identical to that of CPT code 53852, given that the total time is 5 minutes lower, and the post service times are identical. Both the intraservice time ratio between this new CPT code and CPT code 53852 (4.94) and the total time ratio between the two CPT codes (5.72) suggest that the RUC-recommended work RVU of 5.93 overestimates the work involved in furnishing this service. We reviewed other 90-day global CPT codes with similar times and identified CPT code 24071 (Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; 3 cm or greater) with a total time of 183 minutes, intraservice time of 45 minutes, and a work RVU of 5.70 as an appropriate crosswalk. We believe that this is a better reflection of the work involved in furnishing CPT code 538X3, and therefore, we are proposing a work RVU of 5.70 for this CPT code. We welcome comments about the time and intensity required to furnish this new service. Since this CPT code reflects the use of a new technology, it will be reviewed again in 3 years.

For the direct PE inputs, we are proposing to add a new supply (SA128: “kit, Rezum delivery device”), a new equipment item (EQ389: “generator, water thermotherapy procedure”), and updating the price of two supplies (SA036: “kit, transurethral microwave thermotherapy” and SA037: “kit, transurethral needle ablation (TUNA)”) in response to the submission of invoices. We note that these invoices were submitted along with additional information listing the vendor discount for these supplies and equipment. We appreciate the inclusion of the discounted prices on these invoices, and we encourage other invoice submissions to provide the discounted price as well where available. Based on the market research on supply and equipment

pricing carried out by our contractors, we have reason to believe that a vendor discount of 10–15 percent is common on many supplies and equipment. Since we are obligated by statute to establish RVUs for each service as required based on the resource inputs required to furnish the typical case of a service, we have concerns that relying on invoices for supply and equipment pricing absent these vendor discounts may overestimate the resource cost of some services. We encourage the submission of additional invoices that include the discounted price of supplies and equipment to more accurately assess the market cost of these resources. Furthermore, we refer readers to our discussion of the market-based supply and equipment pricing update detailed in section II.B. of this proposed rule.

(25) Vaginal Treatments (CPT Codes 57150 and 57160)

CPT codes 57150 (Irrigation of vagina and/or application of medicament for treatment of bacterial, parasitic, or fungoid disease) and 57160 (Fitting and insertion of pessary or other intravaginal support device) were identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we are proposing the RUC-recommended work RVU of 0.50 for CPT code 57150 and the RUC-recommended work RVU of 0.89 for CPT code 57160.

We are not proposing any direct PE refinements for this code family.

(26) Biopsy of Uterus Lining (CPT Codes 58100 and 58110)

CPT code 58100 (Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. CPT code 58110 (Endometrial sampling (biopsy) performed in conjunction with colposcopy) was also included for review as part of the same family of codes. For CY 2019, we are proposing the RUC-recommended work RVU of 1.21 for CPT code 58100 and the RUC-recommended work RVU of 0.77 for CPT code 58110.

For the direct PE inputs, we are proposing to remove the clinical labor time for the “Review/read post-procedure x-ray, lab and pathology reports” (CA028) activity for CPT code 58100. This code is typically billed with a same day E/M service, and we believe that it would be duplicative to assign clinical labor time for reviewing reports given that this task would typically be done during the same day E/M service. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(27) Injection Greater Occipital Nerve (CPT Code 64405)

CPT code 64405 (Injection, anesthetic agent; greater occipital nerve) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we are proposing the RUC-recommended work RVU of 0.94 for CPT code 64405.

For the direct PE inputs, we are proposing to refine the equipment time for the exam table (EF023) in accordance with our standard equipment time formulas.

(28) Injection Digital Nerves (CPT Code 64455)

CPT code 64455 (Injection(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (e.g., Morton’s neuroma)) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we are proposing the RUC-recommended work RVU of 0.75 for CPT code 64455.

For the direct PE inputs, we are proposing to refine the equipment time for the exam table (EF023) in accordance with our standard equipment time formulas.

(29) Removal of Foreign Body—Eye (CPT Codes 65205 and 65210)

CPT codes 65205 (Removal of foreign body, external eye; conjunctival superficial) and 65210 (Removal of foreign body, external eye; conjunctival embedded (includes concretions), subconjunctival, or scleral nonperforating) were identified as potentially misvalued on a screen of 0-day global services reported with an

E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000.

For CY 2019, we are proposing the RUC-recommended work RVU of 0.49 for CPT code 65205. We note that the recommendations for this code included a statement that the work required to perform CPT code 65205 and the procedure itself had not fundamentally changed since the time of the last review. However, due to the fact that the surveyed intraservice time had decreased from 5 minutes to 3 minutes, the work RVU was lowered from the current value of 0.71 to the recommended work RVU of 0.49, based on a direct crosswalk to CPT code 68200 (Subconjunctival injection). We note that this recommendation appears to have been developed under a methodology similar to our ongoing use of time ratios as one of several methods used to evaluate work. We used time ratios to identify potential work RVUs and considered these work RVUs as potential options relative to the values developed through other options. As we have stated in past rulemaking (such as 82 FR 53032–53033), we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in newly valued work RVUs, as indeed it does not in the case of CPT code 65205 here. Instead, we believed that, since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. We appreciate that the RUC-recommended work RVU for CPT code 65205 has taken these changes in work time into account, and we support the use of similar methodologies, where appropriate, in future work valuations.

For CPT code 65210, we disagree with the RUC-recommended work RVU of 0.75 and we are proposing a work RVU of 0.61 based on a direct crosswalk to CPT code 92511 (Nasopharyngoscopy with endoscope). This crosswalk code has the same intraservice time of 5 minutes and 4 additional minutes of total time as compared to CPT code 65210. We note that the recommended intraservice time for CPT code 65210 is decreasing from 13 minutes to 5 minutes (62 percent reduction), and the recommended total time for CPT code 65210 is decreasing from 25 minutes to 13 minutes (48 percent reduction); however, the RUC-recommended work RVU is only decreasing from 0.84 to 0.75, which is a reduction of about 11 percent. As we noted earlier, we do not believe that the decrease in time as

reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, and we are not proposing a linear decrease in the work valuation based on these time ratios. However, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs, and we do not believe that the recommended work RVU of 0.75 appropriately reflects these decreases in surveyed work time.

Our proposed work RVU of 0.61 is also based on a crosswalk to CPT code 51700 (Bladder irrigation, simple, lavage and/or instillation), another recently reviewed code with higher time values and a work RVU of 0.60. We also note that two injection codes (CPT codes 20551 and 64455) were reviewed at the same RUC meeting as CPT code 65210, each of which shared the same intraservice time of 5 minutes and had a higher total time of 21 minutes. Both of these codes had a RUC-recommended work RVU of 0.75, which we are proposing without refinement for CY 2019. Due to the fact that CPT code 65210 has a lower total time and a lower intensity than both of these injection procedures, we did not agree that CPT code 65210 should be valued at the same work RVU of 0.75. We believe that our proposed work RVU of 0.61 based on a crosswalk to CPT code 92511 is a more accurate value for this code.

For the direct PE inputs, we noted that the RUC-recommended equipment time for the screening lane (EL006) equipment in CPT codes 65205 and 65210 was equal to the total work time in addition to the clinical labor time needed to set up and clean the equipment. We disagree that the screening lane would typically be in use for the total work time, given that this includes the preservice evaluation time and the immediate postservice time. Although we are not currently proposing to refine the equipment time for the screening lane in these two codes, we are soliciting comments on whether the use of the intraservice work time would be more typical than the total work time for CPT codes 65205 and 65210.

(30) Injection—Eye (CPT Codes 67500, 67505, and 67515)

CPT code 67515 (Injection of medication or other substance into Tenon's capsule) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5

years with Medicare utilization greater than 20,000. CPT codes 67500 (Retrobulbar injection; medication (separate procedure, does not include supply of medication)) and 67505 (Retrobulbar injection; alcohol) were also included for review as part of the same family of codes. For CY 2019, we are proposing the RUC-recommended work RVU of 1.18 for CPT code 67500.

For CPT code 67505, we disagree with the RUC-recommended work RVU of 1.18 and we are proposing a work RVU of 0.94 based on a direct crosswalk to CPT code 31575 (Laryngoscopy, flexible; diagnostic). This is a recently reviewed code with the same intraservice time of 5 minutes and 2 fewer minutes of total time as compared to CPT code 67505. We disagreed with the recommendation to propose the same work RVU of 1.18 for both CPT code 67500 and 67505 for several reasons. We noted that the current work RVU of 1.44 for CPT code 67500 is higher than the current work RVU of 1.27 for CPT code 67505, while the current work time of CPT code 67500 is less than the current work time for CPT code 67505. This supported the view that CPT code 67500 should be valued higher than CPT code 67505 due to its greater intensity, which we also found to be supportable on clinical grounds. The typical patient for CPT code 67505 has already lost their sight, and there is less of a concern about accidental blindness as compared to CPT code 67500. At the recommended identical work RVUs, CPT code 67500 has almost triple the intensity of CPT code 67505. Similarly, the intensity does not match our clinical understanding of the complexity and difficulty of the two procedures.

We also noted that the surveyed total time for CPT code 67505 was 7 minutes less than the surveyed time for CPT code 67500, approximately 21 percent lower. If we were to take the total time ratio between the two codes, it would produce a suggested work RVU of 0.93 (26 minutes divided by 33 minutes times a work RVU of 1.18). This time ratio suggested a work RVU almost identical to the 0.94 value that we determined via a crosswalk to CPT code 31575. Based on the preceding rationale, we are proposing a work RVU of 0.94 for CPT code 67505.

For CPT code 67515, we disagree with the RUC-recommended work RVU of 0.84 and we are proposing a work RVU of 0.75 based on a crosswalk to CPT code 64450 (Injection, anesthetic agent; other peripheral nerve or branch). The recommended work RVU is based on a direct crosswalk to CPT code 65222 (Removal of foreign body, external eye;

corneal, with slit lamp) at a work RVU of 0.84. However, the recommended crosswalk code has more than double the intraservice time of CPT code 67515 at 7 minutes, and we believe that it would be more accurate to use a crosswalk to a code with a more similar intraservice time such as CPT code 64450, which is another type of injection procedure. The proposed work RVU of 0.75 is also based on the use of the intraservice time ratio with the first code in the family, CPT code 67500. The intraservice time ratio between these codes is 0.60 (3 minutes divided by 5 minutes), which yields a suggested work RVU of 0.71 when multiplied by the recommended work RVU of 1.18 for CPT code 67500. We believe that this provides further rationale for our proposed work RVU of 0.75 for CPT code 67515.

We are not proposing any direct PE refinements for this code family.

(31) X-Ray Spine (CPT Codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120)

CPT codes 72020 (Radiologic examination, spine, single view, specify level) and 72072 (Radiologic examination, spine; thoracic, 3 views) were identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. The code family was expanded to include ten additional CPT codes to be reviewed together as a group: CPT codes 72040 (Radiologic examination, spine, cervical; 2 or 3 views), 72050 (Radiologic examination, spine, cervical; 4 or 5 views), 72052 (Radiologic examination, spine, cervical; 6 or more views), 72070 (Radiologic examination, spine; thoracic, 2 views), 72074 (Radiologic examination, spine; thoracic, minimum of 4 views), 72080 (Radiologic examination, spine; thoracolumbar junction, minimum of 2 views), 72100 (Radiologic examination, spine, lumbosacral; 2 or 3 views), 72110 (Radiologic examination, spine, lumbosacral; minimum of 4 views), 72114 (Radiologic examination, spine, lumbosacral; complete, including bending views, minimum of 6 views), and 72120 (Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views).

The radiologic examination procedures described by CPT codes 72020 (Radiologic examination, spine, single view, specify level), 72040 (Radiologic examination, spine, cervical; 2 or 3 views), 72050 (Radiologic examination, spine, cervical; 4 or 5 views), 72052

(Radiologic examination, spine, cervical; 6 or more views), 72070 (Radiologic examination, spine; thoracic, 2 views), 72072 (Radiologic examination, spine; thoracic, 3 views), 72074 (Radiologic examination, spine; thoracic, minimum of 4 views), 72080 (Radiologic examination, spine; thoracolumbar junction, minimum of 2 views), 72100 (Radiologic examination, spine, lumbosacral; 2 or 3 views), 72110 (Radiologic examination, spine, lumbosacral; minimum of 4 views), 72114 (Radiologic examination, spine, lumbosacral; complete, including bending views, minimum of 6 views), 72120 (Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views), 72200 (Radiologic examination, sacroiliac joints; less than 3 views), 72202 (Radiologic examination, sacroiliac joints; 3 or more views), 72220 (Radiologic examination, sacrum and coccyx, minimum of 2 views), 73070 (Radiologic examination, elbow; 2 views), 73080 (Radiologic examination, elbow; complete, minimum of 3 views), 73090 (Radiologic examination; forearm, 2 views), 73650 (Radiologic examination; calcaneus, minimum of 2 views), and 73660 (Radiologic examination; toe(s), minimum of 2 views) were all identified as potentially misvalued through a screen for CPT codes with high utilization. With approval from the RUC Research Subcommittee, the specialty societies responsible for reviewing these CPT codes did not conduct surveys, but instead employed a “crosswalk methodology,” in which they derived physician work and time components for CPT codes by comparing them to similar CPT codes. We recognize that a substantial amount of time and effort is involved in conducting surveys of potentially misvalued CPT codes; however, we have concerns about the quality of the underlying data used to value these CPT codes. The descriptors and other information on which the recommendations are based have themselves not been surveyed, in several instances, since 1995. There is no new information about any of these CPT codes that would allow us to detect any potential improvements in efficiency of furnishing the service or evaluate whether changes in practice patterns have affected time and intensity. We are not categorically opposed to changes in process or methodology that might reduce the burden of conducting surveys, but without the benefit of any additional data, through surveys or otherwise, we are not convinced that there is a basis for evaluating the RUC’s

recommendations for work RVUs for each of these CPT codes.

Since all 20 of the CPT codes in this group have very similar intraservice (from 3–5 minutes) and total (ranging from 5–8 minutes) times, we are proposing to use an alternative approach to the valuation of work RVUs for these CPT codes. We calculated the utilization-weighted average RUC-recommended work RVU for the 20 CPT codes. The result of this calculation is a work RVU of 0.23, which we propose to apply uniformly to each CPT code: 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, 72120, 72200, 72202, 72220, 73070, 73080, 73090, 73650, and 73660. We recognize that the proposed work RVU for some of these CPT codes may be somewhat lower at the code level than the RUC’s recommendation, while the proposed work RVU for other CPT codes may be slightly higher than the RUC’s recommended value. We nevertheless believe that the alternative, accepting the RUC’s recommendation for each separate CPT code implies a level of precision about the time and intensity of the CPT codes that we have no way to validate.

For the direct PE inputs, we are proposing to add a patient gown (SB026) supply to CPT code 72120. We noted that all of the other codes in the family that included clinical labor time for the “Greet patient, provide gowning, ensure appropriate medical records are available” (CA009) task included a patient gown, and we are proposing to add the patient gown to match the other codes in the family. We believe that the exclusion of the patient gown for CPT code 72120 was most likely due to a clerical error in the recommendations. We are also proposing to refine the equipment time for the basic radiology room (EL012) in accordance with our standard equipment time formulas.

In our review of the clinical labor time recommended for the “Perform procedure/service—NOT directly related to physician work time” (CA021) task, we noted that the standard convention for this family of codes seemed to be 3 minutes of clinical labor time per view being conducted. For example, CPT code 72020 with a single view had 3 minutes of recommended clinical labor time for this activity, while CPT code 72070 with two views had 6 minutes. However, we also noted that for the codes with 2–3 views such as CPT codes 72040 and 72100, the recommended clinical labor time of 9 minutes appears to assume that 3 views would always be typical for the procedure. The same pattern occurred for codes with 4–5 views, which have a

recommended clinical labor time of 15 minutes (assuming 5 views is typical), and for codes with 6 or more views, which have a recommended clinical labor time of 21 minutes (assuming 7 views is typical).

We are not proposing to refine the clinical labor times for this task as we do not have data available to know how many views would be typical for these CPT codes. However, we note that the intraservice clinical labor time has not changed in roughly 2 decades for these X-ray services, including during this most recent review, and we believe that improving technology during this span of time may have resulted in greater efficiencies in the procedures. We continue to be interested in data sources regarding the intraservice clinical labor times for services such as these that do not match the physician intraservice time, and we welcome any comments that may be able to provide additional details for the twelve codes under review in this family.

(32) X-Ray Sacrum (CPT Codes 72200, 72202, and 72220)

CPT code 72220 (Radiologic examination, sacrum and coccyx, minimum of 2 views) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. CPT codes 72200 (Radiologic examination, sacroiliac joints; less than 3 views) and 72202 (Radiologic examination, sacroiliac joints; 3 or more views) were also included for review as part of the same family of codes. See (31) X-Ray Spine (CPT codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120) for a discussion of proposed work RVUs for these codes.

For the direct PE inputs, we are proposing to refine the equipment time for the basic radiology room (EL012) in accordance with our standard equipment time formulas.

(33) X-Ray Elbow-Forearm (CPT Codes 73070, 73080, and 73090)

CPT codes 73070 (Radiologic examination, elbow; 2 views) and 73090 (Radiologic examination; forearm, 2 views) were identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 73080 (Radiologic examination, elbow; complete, minimum of 3 views) was also included for review as part of the same family of codes. See (31) X-Ray Spine (CPT codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120) above

for a discussion of proposed work RVUs for these codes.

For the direct PE inputs, we are proposing to refine the equipment time for the basic radiology room (EL012) in accordance with our standard equipment time formulas.

(34) X-Ray Heel (CPT Code 73650)

CPT code 73650 (Radiologic examination; calcaneus, minimum of 2 views) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. See (31) X-Ray Spine above for a discussion of proposed work RVUs for these codes.

For the direct PE inputs, we are proposing to refine the equipment time for the basic radiology room (EL012) in accordance with our standard equipment time formulas.

(35) X-Ray Toe (CPT Code 73660)

CPT code 73660 (Radiologic examination; toe(s), minimum of 2 views) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. See (31) X-Ray Spine above for a discussion of proposed work RVUs for these codes.

For the direct PE inputs, we are proposing to add a patient gown (SB026) supply to CPT code 73660. We noted that the other codes in related X-ray code families that included clinical labor time for the "Greet patient, provide gowning, ensure appropriate medical records are available" (CA009) task included a patient gown, and we are proposing to add the patient gown to match the other codes in these families. We are also proposing to refine the equipment time for the basic radiology room (EL012) in accordance with our standard equipment time formulas.

(36) X-Ray Esophagus (CPT Codes 74210, 74220, and 74230)

CPT code 74220 (Radiologic examination; esophagus) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. CPT codes 74210 (Radiologic examination; pharynx and/or cervical esophagus) and 74230 (Swallowing function, with cineradiography/videoradiography) were also included for review as part of the same family of codes.

We are proposing the work RVUs recommended by the RUC for the CPT codes in this family as follows: A work RVU 0.59 for CPT code 74210 (Radiologic examination; pharynx and/or cervical esophagus), a work RVU of 0.67 for CPT code 74220 (Radiologic

examination; esophagus), and a work RVU of 0.53 for CPT code 74230 (Swallowing function, with cineradiography/videoradiography).

For the direct PE inputs, we noted that the recommended quantity of the Polibar barium suspension (SH016) supply is increasing from 1 ml to 150 ml for CPT code 74210 and 100 ml are being added to CPT code 74220, which did not previously include this supply. The RUC recommendation states that this supply quantity increase is due to clinical necessity, but does not go into further details about the typical use of the supply. Although we are not proposing to refine the quantity of the Polibar barium suspension at this time, we are seeking additional comment about the typical use of the supply in these procedures. We are also proposing to refine the equipment times for all three codes in accordance with our standard equipment time formulas.

(37) X-Ray Urinary Tract (CPT Code 74420)

CPT code 74420 (Urography, retrograde, with or without KUB) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually.

We are proposing the RUC-recommended work RVU of 0.52 for CPT code 74420 (Urography, retrograde, with or without KUB).

For the direct PE inputs, we are proposing to remove the 1 minute of clinical labor time for the "Confirm order, protocol exam" (CA014) activity. The clinical labor time recommended for this activity is not included in the reference code, nor is it included in any of the two dozen other X-ray codes that were reviewed at the same RUC meeting. There is also no explanation in the recommended materials as to why this clinical labor time would need to be added. We do not believe that this clinical labor would be typical for CPT code 74420, and we are proposing to remove it to match the rest of the X-ray codes. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(38) Fluoroscopy (CPT Code 76000)

CPT code 76000 (Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health care professional time) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 76001 (Fluoroscopy, physician or other qualified health care professional time more than 1 hour, assisting a nonradiologic physician or other qualified health care professional) was

also included for review as part of the same family of codes. However, due to the fact that supervision and interpretation services have been increasingly bundled into the underlying procedure codes, the RUC concluded that this practice is rare, if not obsolete, and CPT code 76001 was recommended for deletion by the CPT Editorial Panel for CY 2019.

We are proposing the RUC-recommended work RVU of 0.30 for CPT code 76000 (Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health care professional time, other than 71023 or 71034 (e.g., cardiac fluoroscopy)).

For the direct PE inputs, we are proposing to refine the equipment times in accordance with our standard equipment time formulas.

(39) Echo Exam of Eye Thickness (CPT Code 76514)

CPT code 76514 (Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness)) was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWP/UT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard-valued and CMS/Other source codes.

For CPT code 76514, we disagree with the RUC-recommended work RVU of 0.17 and we are proposing a work RVU of 0.14. We note that the recommended intraservice time for CPT code 76514 is decreasing from 5 minutes to 3 minutes (40 percent reduction), and the recommended total time for CPT code 76514 is decreasing from 15 minutes to 5 minutes (67 percent reduction); however, the RUC-recommended work RVU is not decreasing at all and remains at 0.17. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs.

We also note that the RUC recommendations for CPT code 76514 stated that, although the steps in the procedure are unchanged since it was first valued, the workflow has changed. With the advent of smaller and easier to use pachymeters, the technician now typically takes the measurements that used to be taken by the practitioner for CPT code 76514, and the intraservice time was reduced by two minutes to account for the technician performing

this service. We believe that this change in workflow indicates that the work RVU for the code should be reduced in some fashion, since some of the work that was previously done by the practitioner is now typically performed by the technician. We have no reason to believe that there is more intensive cognitive work being performed by the practitioner after these measurements are taken since the recommendations indicated that the steps in the procedure are unchanged since this code was first valued.

Therefore, we are proposing a work RVU of 0.14 for CPT code 76514, which is based on taking half of the intraservice time ratio. We considered applying the intraservice time ratio to CPT code 76514, which would reduce the work RVU to 0.10 based on taking the change in intraservice time (from 5 minutes to 3 minutes) and multiplying this ratio of 0.60 times the current work RVU of 0.17. However, we recognize that the minutes shifted to the clinical staff were less intense than the minutes that remained in CPT code 76514, and therefore, we applied half of the intraservice time ratio for a reduction of 0.03 RVUs to arrive at a proposed work RVU of 0.14. We believe that this proposed value more accurately takes into account the changes in workflow that have caused substantial reductions in the surveyed work time for the procedure.

We are not proposing any direct PE refinements for this code family.

(40) Ultrasound Elastography (CPT Codes 767X1, 767X2, and 767X3)

In September 2017, the CPT Editorial Panel created three new codes describing the use of ultrasound elastography to assess organ parenchyma and focal lesions: CPT codes 767X1 (Ultrasound, elastography; parenchyma), 767X2 (Ultrasound, elastography; first target lesion) and 767X3 (Ultrasound, elastography; each additional target lesion). The most common use of this code set will be for preparing patients with disease of solid organs, like the liver, or lesions within solid organs.

The RUC recommended a work RVU of 0.59 for CPT code 767X1 (Ultrasound, elastography; parenchyma (e.g., organ)), a work RVU of 0.59 for CPT code 767X2 (Ultrasound, elastography; first target lesion), and a work RVU of 0.50 for add-on CPT code 767X3 (Ultrasound, elastography; each additional target lesion). We are proposing the RUC-recommended work RVUs for each of these new CPT codes.

For the direct PE inputs, we are proposing to refine the clinical labor

time for the “Prepare room, equipment and supplies” (CA013) activity to 3 minutes and to refine the clinical labor time for the “Confirm order, protocol exam” (CA014) activity to 0 minutes for CPT codes 767X1 and 767X2. CPT code 76700 (Ultrasound, abdominal, real time with image documentation; complete), the reference code for these two new codes, did not previously have clinical labor time assigned for the “Confirm order, protocol exam” clinical labor task, and we do not have any reason to believe that these particular services being furnished by the clinical staff have changed in the new codes, only the way in which this clinical labor time has been presented on the PE worksheets. We also note that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished in CPT codes 767X1 and 767X2. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(41) Ultrasound Exam—Scrotum (CPT Code 76870)

CPT code 76870 (Ultrasound, scrotum and contents) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. We are proposing a work RVU of 0.64 for CPT code 76870 (Ultrasound, scrotum and contents), as recommended by the RUC.

For the direct PE inputs, we are proposing to refine the clinical labor time for the “Prepare room, equipment and supplies” (CA013) activity to 3 minutes and to refine the clinical labor time for the “Confirm order, protocol exam” (CA014) activity to 0 minutes. CPT code 76870 did not previously have clinical labor time assigned for the “Confirm order, protocol exam” clinical labor task, and we do not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets. We also note that there is no effect on the total clinical labor direct costs in these situations since the same 3 minutes of clinical labor time is still being furnished under the CA013 room preparation activity. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(42) Contrast-Enhanced Ultrasound (CPT Codes 76X0X and 76X1X)

In September 2017, the CPT Editorial Panel created two new CPT codes describing the use of intravenous microbubble agents to evaluate

suspicious lesions by ultrasound. CPT code 76X0X (Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion) is a stand-alone procedure for the evaluation of a single target lesion. CPT code 76X1X (Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection) is an add-on code for the evaluation of each additional lesion.

The two new CPT codes in this family represent a new technology that involves the use of intravenous microbubble agents to evaluate suspicious lesions by ultrasound. The first new CPT code, 76X0X (Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion), is the base code for the new add-on CPT code 76X1X (Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection). The RUC reviewed the survey results for CPT code 76X0X and recommended total time of 30 minutes and intraservice time of 20 minutes. Their recommendation for a work RVU of 1.62 is based neither on the median of the survey results (1.82) nor the 25th percentile of the survey results (1.27). Instead, the RUC-recommended work RVU is based on a crosswalk to CPT code 73719 (Magnetic resonance (e.g., proton) imaging, lower extremity other than joint; with contrast material(s)), which has identical intraservice and total times as the survey CPT code. The RUC also identified a comparison CPT code (CPT code 73222 (Magnetic resonance (e.g., proton) imaging, any joint of upper extremity; with contrast material(s)) with work RVU 1.62 and similar times. For add-on CPT code 76X1X, the RUC recommended a work RVU of 0.85, which is the 25th percentile of survey results, with total and intraservice times of 15 minutes.

While we generally agree that, particularly in instances where a CPT code represents a new technology or procedure, there may be reason to deviate from survey metrics, we are confused by the logic behind the RUC's recommendation of a work RVU of 1.62 for CPT code 76X0X. When we consider the range of existing CPT codes with 30 minutes total time and 20 minutes intraservice time, we note that a work RVU of 1.62 is among the highest potential crosswalks. We also note that the RUC agreed with the 25th percentile of survey results for the new add-on CPT code, 76X1X, and we do not see why the 25th percentile wouldn't also

be appropriate for the base CPT code, 76X0X. Therefore, we are proposing a work RVU of 1.27 for CPT code 76X0X. We identified two CPT codes with total time of 30 minutes and intraservice time of 20 minutes that bracket the proposed work RVU of 1.27: CPT code 93975 (Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study) has a work RVU of 1.16, and CPT code 72270 (Myelography, 2 or more regions (e.g., lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical), radiological supervision and interpretation) has a work RVU of 1.33. We are proposing the RUC-recommended work RVU of 0.85 for add-on CPT code 76X1X.

For the direct PE inputs, we are proposing to refine the clinical labor time for the "Prepare room, equipment and supplies" (CA013) activity to 3 minutes and to refine the clinical labor time for the "Confirm order, protocol exam" (CA014) activity to 0 minutes for CPT code 76X0X. CPT codes 76700 (Ultrasound, abdominal, real time with image documentation; complete) and 76705 (Ultrasound, abdominal, real time with image documentation; limited), the reference codes for this new code, did not previously have clinical labor time assigned for the "Confirm order, protocol exam" clinical labor task, and we do not have any reason to believe that these particular services being furnished by the clinical staff have changed in the new code, only the way in which this clinical labor time has been presented on the PE worksheets. We also note that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished in CPT code 76X0X.

We are proposing to remove the 50 ml of the phosphate buffered saline (SL180) for CPT codes 76X0X and 76X1X. When these codes were reviewed by the RUC, the conclusion that was reached was to remove this supply and replace it with normal saline. Since the phosphate buffered saline remained in the recommended direct PE inputs, we believe its inclusion may have been a clerical error. We are proposing to remove the supply and soliciting comments on the phosphate buffered saline or a replacement saline solution. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(43) Magnetic Resonance Elastography (CPT Code 76X01)

The CPT Editorial Panel created a new stand-alone code (76X01)

describing the use of magnetic resonance elastography for the evaluation of organ parenchymal pathology. This code will most often be used to evaluate patients with disease of solid organs (for example, cirrhosis of the liver) or pathology within solid organs that manifest with increasing fibrosis or scarring. The goal with magnetic resonance elastography is to evaluate the degree of fibrosis/scarring (that is, stiffness) without having to perform more invasive procedures (for example, biopsy). This technique can be used to characterize the severity of parenchymal disease, follow disease progression, or response to therapy.

The RUC recommended a work RVU for new CPT code 76X01 (Magnetic resonance (e.g., vibration) elastography) of 1.29, with 15 minutes of intraservice time and 25 minutes of total time. The recommendation is based on a comparison with two reference CPT codes, CPT code 74183 (Magnetic resonance (e.g., proton) imaging, abdomen; without contrast material(s), followed by with contrast material(s) and further sequences) with total time of 40 minutes, intraservice time of 30 minutes, and a work RVU of 2.20; and CPT code 74181 (Magnetic resonance (e.g., proton) imaging, abdomen; without contrast material(s)), which has a total time of 30 minutes, intraservice time of 20 minutes, and a work RVU of 1.46. The RUC stated that both reference CPT codes have higher work values than the new CPT code, which is justified in both cases by higher intra-service times. They note that, despite shorter intraservice and total time, CPT code 76X01 is slightly more intense to perform due to the evaluation of wave propagation images and quantitative stiffness measures. We do not agree with the RUC's recommended work RVU for this CPT code. Using the RUC's two top reference CPT codes as a point of comparison, the intraservice time ratio in both instances suggests that a work RVU closer to 1.10 would be more appropriate. We recognize that the RUC believes the new CPT code is slightly more intense to furnish, but we are concerned about the relativity of this code in comparison with other imaging procedures that have similar intraservice and total times. Instead of the RUC-recommended work RVU of 1.29 for CPT code 76X01, we are proposing a work RVU of 1.10, which is based on a direct crosswalk to CPT code 71250 (Computed tomography, thorax; without contrast material). CPT code 71250 has identical intraservice time (15 minutes) and total time (25 minutes) compared to CPT code 76X01, and we

believe that the work involved in furnishing both services is similar. We note that CPT code 76X01 describes a new technology and will be reviewed again by the RUC in 3 years.

For the direct PE inputs, we are proposing to refine the clinical labor time for the “Prepare room, equipment and supplies” (CA013) activity from 6 minutes to 5 minutes, and for the “Prepare, set-up and start IV, initial positioning and monitoring of patient” (CA016) activity from 4 minutes to 3 minutes. We disagree that this additional clinical labor time would be typical for these activities, which are already above the standard times for these tasks. In both cases, we propose to maintain the current time from the reference CPT code 72195 (Magnetic resonance (e.g., proton) imaging, pelvis; without contrast material(s)) for these clinical labor activities. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(44) Computed Tomography (CT) Scan for Needle Biopsy (CPT Code 77012)

CPT code 77012 (Computed tomography guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), radiological supervision and interpretation) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually.

We are proposing the RUC-recommended work RVU of 1.50 for CPT code 77012 (Computed tomography guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), radiological supervision and interpretation).

For the direct PE inputs, we are proposing to refine the clinical labor time for the “Prepare room, equipment and supplies” (CA013) activity to 3 minutes and to refine the clinical labor time for the “Confirm order, protocol exam” (CA014) activity to 0 minutes. CPT code 77012 did not previously have clinical labor time assigned for the “Confirm order, protocol exam” clinical labor task, and we do not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets. We also note that there is no effect on the total clinical labor direct costs in these situations since the same 3 minutes of clinical labor time is still being furnished under the CA013 room preparation activity.

We are proposing to refine the equipment time for the CT room (EL007) to maintain the current time of 9

minutes. CPT code 77012 is a radiological supervision and interpretation procedure and there has been a longstanding convention in the direct PE inputs, shared by 38 other codes, to assign an equipment time of 9 minutes for the equipment room in these procedures. We do not believe that it would serve the interests of relativity to increase the equipment time for the CT room in CPT code 77012 without also addressing the equipment room time for the other radiological supervision and interpretation procedures. Therefore, we are proposing to maintain the current equipment room time of 9 minutes until this group of procedures can be subject to a more comprehensive review. We are also proposing to refine the equipment time for the Technologist PACS workstation (ED050) in accordance with our standard equipment time formulas.

(45) Dual-Energy X-Ray Absorptiometry (CPT Code 77081)

CPT code 77081 (Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)) was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWP/UT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. For CY 2019, we are proposing the RUC-recommended work RVU of 0.20 for CPT code 77081.

We are not proposing any direct PE refinements for this code family.

(46) Breast MRI With Computer-Aided Detection (CPT Codes 77X49, 77X50, 77X51, and 77X52)

CPT codes 77058 (Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral) and 77059 (Magnetic resonance imaging, breast, without and/or with contrast material(s); bilateral) were identified in 2016 on a high expenditure services screen across specialties with Medicare allowed charges of \$10 million or more. When preparing to survey these codes, the specialties noted that the clinical indications had changed for these exams. The technology had advanced to make computer-aided detection (CAD) typical and these codes did not parallel the structure of other magnetic resonance imaging (MRI) codes. In June 2017 the CPT Editorial Panel deleted CPT codes 0159T, 77058, and 77059 and created four new CPT codes to report breast MRI with and without contrast (including computer-aided detection).

The RUC recommended a work RVU of 1.45 for CPT code 77X49 (Magnetic resonance imaging, breast, without contrast material; unilateral). This recommendation is based on a comparison with CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast material) and 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)), which both have similar intraservice and total times in relation to CPT code 77X49. We disagree with the RUC’s recommended work RVU because we do not believe that the reduction in total time of 15 minutes between the new CPT code 77X49 and the deleted CPT code 74177 is adequately reflected in its recommendation. While total time has decreased by 15 minutes, the only other difference between the two CPT codes is the change in the descriptor from the phrase ‘without and/or with contrast material(s)’ to ‘without contrast material,’ suggesting that there is less work involved in the new CPT code than in the deleted CPT code. Instead, we are proposing a work RVU of 1.15 for CPT code 77X49, which is similar to the total time ratio between the new CPT code and the deleted CPT code. It is also supported by a crosswalk to CPT code 77334 (Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)). CPT code 77334 has total time of 35 minutes, intraservice time of 30 minutes, and a work RVU of 1.15.

CPT code 77X50 (Magnetic resonance imaging, breast, without contrast material; bilateral) describes the same work as CPT code 77X49, but reflects a bilateral rather than the unilateral procedure. The RUC recommended a work RVU of 1.60 for CPT code 77X50. Since we are proposing a different work RVU for the unilateral procedure than the value proposed by the RUC, we believe it is appropriate to recalibrate the work RVU for CPT code 77X50 relative to the RUC’s recommended difference in work between the two CPT codes. The RUC’s recommendation for the bilateral procedure is 0.15 work RVUs larger than for the unilateral procedure. Therefore, we are proposing a work RVU of 1.30 for CPT code 77X50.

The RUC recommended a work RVU of 2.10 for CPT code 77X51 (Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD-real time lesion detection, characterization and pharmacokinetic analysis) when performed; unilateral). CPT code 77X51 is a new CPT code that bundles the deleted CPT code for unilateral breast

MRI without and/or with contrast material(s) with CAD, which was previously reported, in addition to the primary procedure CPT code, as CPT code 0159T (computer aided detection, including computer algorithm analysis of MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation, breast MRI).

Consistent with our belief that the proposed value for the base CPT code in this series of new CPT codes (CPT code 77X49) should be a work RVU of 1.15, we are proposing a work RVU for CPT code 77X51 that adds the RUC-recommended difference in RUC-recommended work RVUs between CPT codes 77X49 and 77X51 (0.65 work RVUs) to the proposed work RVU for CPT code 77X49. Therefore, we are proposing a work RVU of 1.80 for CPT code 77X51.

The last new CPT code in this series, CPT code 77X52 (Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD-real time lesion detection, characterization and pharmacokinetic analysis) when performed; bilateral) describes the same work as CPT code 77X51, but reflects a bilateral rather than a unilateral procedure. The RUC recommended a work RVU of 2.30 for this CPT code. Similar to the process for valuing work RVUs for CPT code 77X50 and CPT code 77X51, we believe that a more appropriate work RVU is calculated by adding the difference in the RUC recommended work RVU for CPT codes 77X49 and 77X52, to the proposed value for CPT code 77X49. Therefore, we are proposing a work RVU of 2.00 for CPT code 77X52.

For the direct PE inputs, we are proposing to refine the clinical labor time for the "Prepare, set-up and start IV, initial positioning and monitoring of patient" (CA016) activity from 7 minutes to 3 minutes for CPT codes 77X49 and 77X50, and from 9 minutes to 5 minutes for CPT codes 77X51 and 77X52. We note that when the MRI of Lower Extremity codes were reviewed during the previous rule cycle (CPT codes 73718–73720), these codes contained either 3 minutes or 5 minutes of recommended time for this same clinical labor activity. We also note that the current Breast MRI codes that are being deleted and replaced with these four new codes, CPT codes 77058 and 77059, contain 5 minutes of clinical labor time for this same activity. We have no reason to believe that the new codes would require additional clinical labor time for patient positioning, especially given that the recommended

clinical labor times are decreasing in comparison to the reference codes for obtaining patient consent (CA011) and preparing the room (CA013). Therefore, we are refining the clinical labor time for the CA016 activity as detailed above to maintain relativity with the current clinical labor times in the reference codes, as well as with other recently reviewed MRI procedures.

Included in the recommendations for this code family were five new equipment items: CAD Server (ED057), CAD Software (ED058), CAD Software—Additional User License (ED059), Breast coil (EQ388), and CAD Workstation (CPU + Color Monitor) (ED056). We did not receive any invoices for these five equipment items, and as such we do not have any direct pricing information to use in their valuation. We are proposing to use crosswalks to similar equipment items as proxies for three of these new types of equipment until we do have pricing information:

- CAD software (ED058) is crosswalked to flow cytometry analytics software (EQ380).
- Breast coil (EQ388) is crosswalked to Breast biopsy device (coil) (EQ371).
- CAD Workstation (CPU + Color Monitor) (ED056) is crosswalked to Professional PACS workstation (ED053).

We welcome the submission of invoices with pricing information for these three new equipment items for our consideration to replace the use of these proxies. For the other two equipment items (CAD Server (ED057) and CAD Software—Additional User License (ED059)), we are not proposing to establish a price at this time as we believe both of them would constitute forms of indirect PE under our methodology. We do not believe that the CAD Server or Additional User License would be allocated to the use of an individual patient for an individual service, and can be better understood as forms of indirect costs similar to office rent or administrative expenses. We understand that as the PE data age, these issues involving the use of software and other forms of digital tools become more complex. However, the use of new technology does not change the statutory requirement under which indirect PE is assigned on the basis of direct costs that must be individually allocable to a particular patient for a particular service. We look forward to continuing to seek out new data sources to help in updating the PE methodology.

We are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

(47) Blood Smear Interpretation (CPT Code 85060)

CPT code 85060 (Blood smear, peripheral, interpretation by physician with written report) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. For CY 2019, the RUC recommended a work RVU of 0.45 based on maintaining the current work RVU.

We disagree with the recommended value and are proposing a work RVU of 0.36 for CPT code 85060 based on the total time ratio between the current time of 15 minutes and the recommended time established by the survey of 12 minutes. This ratio equals 80 percent, and 80 percent of the current work RVU of 0.45 equals a work RVU of 0.36. When we reviewed CPT code 85060, we found that the recommended work RVU was higher than nearly all of the other global XXX codes with similar time values, and we do not believe that this blood smear interpretation procedure would have an anomalously high intensity. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 85060, we believe that it would be more accurate to propose the total time ratio at a work RVU of 0.36 to account for these decreases in the surveyed work time.

The proposed work RVU is also based on the use of three crosswalk codes. We are directly supporting the proposed valuation through a crosswalk to CPT code 95930 (Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report), which has a work RVU of 0.35 along with 10 minutes of intraservice time and 14 minutes of total time. We also explain the proposed valuation by bracketing it between two other crosswalks, with CPT code 99152 (Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intraservice time, patient age 5 years or older) on the lower end at a work RVU of 0.25 and CPT code 93923 (Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels, or single level study with provocative

functional maneuvers) on the higher end at a work RVU of 0.45.

The RUC recommended no direct PE inputs for CPT code 85060 and we are recommending none.

(48) Bone Marrow Interpretation (CPT Code 85097)

CPT code 85097 (Bone marrow, smear interpretation) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. For CY 2019, the RUC recommended a work RVU of 1.00 based on a direct crosswalk to CPT code 88121 (Cytopathology, in situ hybridization (*e.g.*, FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; using computer-assisted technology).

We disagree with the RUC-recommended value and we are proposing a work RVU of 0.94 for CPT code 85097 based on maintaining the current work valuation. We noted that the survey indicated that CPT code 85097 typically takes 25 minutes of work time to perform, down from a previous work time of 30 minutes, and, generally speaking, since the two components of work are time and intensity, we believe that significant decreases in time should be reflected in decreases to work RVUs. For the specific case of CPT code 85097, we are supporting our proposed work RVU of 0.94 through a crosswalk to CPT code 88361 (Morphometric analysis, tumor immunohistochemistry (*e.g.*, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology), a recently reviewed code from CY 2018 with the identical time values and a work RVU of 0.95.

We also considered a work RVU of 0.90 based on double the recommended work RVU of 0.45 for CPT code 85060 (Blood smear, peripheral, interpretation by physician with written report). When both of these CPT codes were under review, the explanation was offered that in a peripheral blood smear, typically, the practitioner does not have the approximately 12 precursor cells to review, whereas in an aspirate from the bone marrow, the practitioner is examining all the precursor cells. Additionally, for CPT code 85097, there are more cell types to look at as well as more slides, usually four, whereas with CPT code 85060 the practitioner would typically only look at one slide. While we do not propose to value CPT code 85097 at twice the work RVU of CPT code 85060, we believe this analysis also supports maintaining the current

work RVU of 0.94 as opposed to raising it to 1.00.

For the direct PE inputs, we are proposing to remove the clinical labor time for the “Accession and enter information” (PA001) and “File specimen, supplies, and other materials” (PA008) activities. As we stated previously, information entry and specimen filing tasks are not individually allocable to a particular patient for a particular service and are considered to be forms of indirect PE. While we agree that these are necessary tasks, under our established methodology we believe that they are more appropriately classified as indirect PE.

(49) Fibrinolysins Screen (CPT Code 85390)

CPT code 85390 (Fibrinolysins or coagulopathy screen, interpretation and report) was identified as potentially misvalued on a screen of codes with a negative IWPOT, with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. For CY 2019, we are proposing the RUC-recommended work RVU of 0.75 for CPT code 85390.

Because this is a work only code, the RUC did not recommend, and we are not proposing any direct PE inputs for CPT code 85390.

(50) Electroretinography (CPT Codes 92X71, 92X73, and 03X0T)

CPT code 92275 (Electroretinography with interpretation and report) was identified in 2016 on a high expenditure services screen across specialties with Medicare allowed charges of \$10 million or more. In January 2016, the specialty society noted that they became aware of inappropriate use of CPT code 92275 for a less intensive version of this test for diagnosis and indications that are not clinically proven and for which less expensive and less intensive tests already exist. CPT changes were necessary to ensure that the service for which CPT code 92275 was intended was clearly described, as well as an accurate vignette and work descriptor were developed. In September 2017, the CPT Editorial Panel deleted CPT code 92275 and replaced it with two new codes to describe electroretinography full field and multi focal. A category III code was retained for pattern electroretinography.

For CPT code 92X71 (Electroretinography (ERG) with interpretation and report; full field (*e.g.*, fERG, flash ERG, Ganzfeld ERG)), we disagree with the recommended work RVU of 0.80 and we are instead

proposing a work RVU of 0.69 based on a direct crosswalk to CPT code 88172 (Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode, each site). CPT code 88172 is another interpretation procedure with the same 20 minutes of intraservice time, which we believe is a more accurate comparison for CPT code 92X71 than the two reference codes chosen by the survey participants due to their significantly higher and lower intraservice times. We note that the recommended intraservice time for CPT code 92X71 as compared to its predecessor CPT code 92275 is decreasing from 45 minutes to 20 minutes (56 percent reduction), and the recommended total time is decreasing from 71 minutes to 22 minutes (69 percent reduction); however, the work RVU is only decreasing from 1.01 to 0.80, which is a reduction of just over 20 percent. Although we do not imply that the decreases in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 92X71, we have reason to believe that the significant drops in surveyed work time as compared to CPT code 92275 are a result of improvements in technology since the predecessor code was reviewed. The older machines used for electroretinography were slower and more cumbersome, and now the same work for the service can be performed in significantly less time. Therefore, we are proposing a work RVU of 0.69 based on the direct crosswalk to CPT code 88172, which we believe more accurately accounts for these decreases in surveyed work time.

For CPT code 92X73 (Electroretinography (ERG) with interpretation and report; multifocal (mfERG)), we disagree with the RUC-recommended work RVU of 0.72 and are proposing a work RVU of 0.61. We concur that the relative difference in work between CPT code 92X71 and 92X73 is equivalent to the recommended interval of 0.08 RVUs. Therefore, we are proposing a work RVU of 0.61 for CPT code 92X73, based on the recommended interval of 0.08 fewer RVUs below our proposed work RVU of 0.69 for CPT code 92X71. The proposed work RVU is also based on the use of two crosswalk codes: CPT code 88387 (Macroscopic examination, dissection, and preparation of tissue for

non-microscopic analytical studies; each tissue preparation); and CPT code 92100 (Serial tonometry (separate procedure) with multiple measurements of intraocular pressure over an extended time period with interpretation and report, same day). Both codes share the same 20 minutes of intraservice and 20 minutes of total time, with a work RVU of 0.62 for CPT code 88387 and a work RVU of 0.61 for CPT code 92100.

The recommendations for this code family also include Category III code 03X0T (Electroretinography (ERG) with interpretation and report, pattern (PERG)). We typically assign contractor pricing for Category III codes since they are temporary codes assigned to emerging technology and services. However, in cases where there is an unusually high volume of services that will be performed under a Category III code, we have sometimes assigned an active status to the procedure and developed RVUs before a formal CPT code is created. In the case of Category III code 03X0T, the recommendations indicate that approximately 80 percent of the services currently reported under CPT code 92275 will be reported under the new Category III code. Since this will involve an estimated 100,000 services for CY 2019, we believe that the interests of relativity would be better served by assigning an active status to Category III code 03X0T and creating RVUs through the use of a proxy crosswalk to a similar existing service. Therefore, we are proposing to assign an active status to Category III code 03X0T for CY 2019, with a work RVU and work time values crosswalked from CPT code 92250 (Fundus photography with interpretation and report). CPT code 92250 is a clinically similar procedure that was recently reviewed during the CY 2017 rule cycle. We are proposing a work RVU of 0.40 and work times of 10 minutes of intraservice and 12 minutes of total time for Category III code 03X0T based on this crosswalk to CPT code 92250.

For the direct PE inputs, we are proposing to remove the preservice clinical labor in the facility setting for CPT codes 92X71 and 92X73. Both of these codes are diagnostic tests under which the professional (26 modifier) and technical (TC modifier) components will be separately billable, and codes that have these professional and technical components typically will not have direct PE inputs in the facility setting since the technical component is only valued in the nonfacility setting. We also note on this subject that the predecessor code, CPT code 92275, does not currently include any preservice

clinical labor, nor any facility direct PE inputs.

We are proposing to remove the clinical labor time for the “Greet patient, provide gowning, ensure appropriate medical records are available” (CA009) and the “Provide education/obtain consent” (CA011) activities for CPT codes 92X71 and 92X73. Both of these CPT codes will typically be reported with a same day E/M service, and we believe that these clinical labor tasks will be carried out during the E/M service. We believe that their inclusion in CPT codes 92X71 and 92X73 would be duplicative. We are also proposing to refine the clinical labor time for the “Prepare room, equipment and supplies” (CA013) activity to 3 minutes and to refine the clinical labor time for the “Confirm order, protocol exam” (CA014) activity to 0 minutes for both codes. The predecessor CPT code 92275 did not previously have clinical labor time assigned for the “Confirm order, protocol exam” clinical labor task, and we do not have any reason to believe that the services being furnished by the clinical staff have changed in the new codes, only the way in which this clinical labor time has been presented on the PE worksheets. We also note that there is no effect on the total clinical labor direct costs in these situations since the same 3 minutes of clinical labor time is still being furnished.

We are proposing to refine the clinical labor time for the “Clean room/equipment by clinical staff” (CA024) activity from 12 minutes to 8 minutes for CPT codes 92X71 and 92X73. The recommendations for these codes stated that cleaning is carried out in several steps: The patient is first cleaned for 2 minutes, followed by wires and electrodes being scrubbed carefully with detergent, soaked, and then rinsed with sterile water. We agree with the need for 2 minutes of patient cleaning time and for the cleaning of the wires and electrodes to take place in two different steps. However, our standard clinical labor time for room/equipment cleaning is 3 minutes, and therefore, we are proposing a total time of 8 minutes for these codes, based on 2 minutes for patient cleaning and then 3 minutes for each of the two steps of wire and electrode cleaning.

We are proposing to refine the clinical labor time for the “Technologist QC’s images in PACS, checking for all images, reformat, and dose page” (CA030) activity from 10 minutes to 3 minutes for CPT codes 92X71 and 92X73. We finalized in the CY 2017 PFS final rule (81 FR 80184–80186) a range of appropriate standard minutes for this

clinical labor activity, ranging from 2 minutes for simple services up to 5 minutes for highly complex services. We believe that the complexity of the imaging in CPT codes 92X71 and 92X73 is comparable to the CT and magnetic resonance (MR) codes that have been recently reviewed, such as CPT code 76X01 (Magnetic resonance (e.g., vibration) elastography). Therefore, in order to maintain relativity, we are proposing the same clinical labor time of 3 minutes for CPT codes 92X71 and 92X73 that has been recommended for these CT and MR codes. We are also proposing to refine the clinical labor time for the “Review examination with interpreting MD/DO” (CA031) activity from 5 minutes to 2 minutes for CPT codes 92X71 and 92X73. We also finalized in the CY 2017 PFS final rule a standard time of 2 minutes for reviewing examinations with the interpreting MD, and we have no reason to believe that these codes would typically require additional clinical labor at more than double the standard time.

We noted that the new equipment item “Contact lens electrode for mfERG and ffERG” (EQ391) was listed twice for CPT code 92X71 but only a single time for CPT code 92X73. We are seeking additional information about whether the recommendations intended this equipment item to be listed twice, with one contact intended for each eye, or whether this was a clerical mistake. We are also interested in additional information as to why the contact lens electrode was listed twice for CPT code 92X71 but only a single time for CPT code 92X73. Finally, we are also proposing to refine the equipment times in accordance with our standard equipment time formulas.

We are proposing to use the direct PE inputs for CPT code 92X73, including the refinements detailed above, as a proxy for Category III code 03X0T until it can be separately reviewed by the RUC.

(51) Cardiac Output Measurement (CPT Codes 93561 and 93562)

CPT codes 93561 (Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; with cardiac output measurement) and 93562 (Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; subsequent measurement of cardiac output) were identified as potentially misvalued on a screen of codes with a negative IWPUP, with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for

Harvard valued and CMS/Other source codes. The specialty societies noted that CPT codes 93561 and 93562 are primarily performed in the pediatric population, thus the Medicare utilization for these Harvard-source services is not over 1,000. However, the specialty societies requested and the RUC agreed that these services should be reviewed under this negative IWPOT screen.

For CPT code 93561, we disagree with the RUC-recommended work RVU of 0.95 and we are proposing a work RVU of 0.60 based on a crosswalk to CPT code 77003 (Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural or subarachnoid)). CPT Code 77003 is another recently-reviewed add-on global code with the same 15 minutes of intraservice time and 2 additional minutes of preservice evaluation time. In our review of CPT code 93561, we found that there was a particularly unusual relationship between the surveyed work times and the RUC-recommended work RVU. We noted that the recommended intraservice time for CPT code 93561 is decreasing from 29 minutes to 15 minutes (48 percent reduction), and the recommended total time for CPT code 93561 is decreasing from 78 minutes to 15 minutes (81 percent reduction); however, the recommended work RVU is instead increasing from 0.25 to 0.95, which is an increase of nearly 300 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should typically be reflected in decreases to work RVUs, not increases in valuation. We recognize that CPT code 93561 is an unusual case, as it is shifting from 0-day global status to add-on code status. However, when the work time for a code is going down and the unit of service is being reduced, we would not expect to see an increased work RVU under these circumstances, and especially not such a large work RVU increase. Therefore, we are proposing instead to crosswalk CPT code 93561 to CPT code 77003 at a work RVU of 0.60, which we believe is a more accurate valuation in relation to other recently-reviewed add-on codes on the PFS. We believe that this proposed work RVU of 0.60 better preserves relativity with other clinically similar codes with similar surveyed work times.

For CPT code 93562, we disagree with the recommended work RVU of 0.77

and are proposing a work RVU of 0.48 based on the intraservice time ratio with CPT code 93561. We observed a similar pattern taking place with CPT code 93562 as with the first code in the family, noting that the recommended intraservice time is decreasing from 16 minutes to 12 minutes (25 percent reduction), and the recommended total time is decreasing from 44 minutes to 12 minutes (73 percent reduction); however, the RUC-recommended work RVU is instead increasing from 0.01 to 0.77. We recognize that CPT code 93562 is another unusual case, as it is also shifting from 0-day global status to add-on code status, and the current work RVU of 0.01 was a decrease from the code's former valuation of 0.16 following the removal of moderate sedation in the CY 2017 rule cycle. However, when the work time for a code is going down and the unit of service is being reduced, we typically would not expect to see a work RVU increase under these circumstances, and especially not such a large work RVU increase. Therefore, we are proposing instead to apply the intraservice time ratio from CPT code 93561, for a ratio of 0.80 (12 minutes divided by 15 minutes) multiplied by the proposed work RVU of 0.60 for CPT code 93561, which results in the proposed work RVU of 0.48 for CPT code 93562. We note that the RUC-recommended work values also line up according to the same intraservice time ratio, with the recommended work RVU of 0.77 for CPT code 93562 existing in a ratio of 0.81 with the recommended work RVU of 0.95 for CPT code 93561. We believe that this provides further rationale for our proposal to value the work RVU of CPT code 93562 at 80 percent of the work RVU of CPT code 93561.

There are no recommended direct PE inputs for the codes in this family and we are not proposing any direct PE inputs.

(52) Coronary Flow Reserve Measurement (CPT Codes 93571 and 93572)

CPT code 93571 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel) was identified on a list of all services with total Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2009 through 2014. CPT code 93572 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including

pharmacologically induced stress; each additional vessel) was also included for review as part of the same family of CPT codes. The RUC recommended a work RVU of 1.50 for CPT code 93571, which is lower than the current work RVU of 1.80. The total time for this service decreased by 5 minutes from 20 minutes to 15 minutes. The RUC's recommendation is based on a crosswalk to CPT code 15136 (Dermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof), which has an identical intraservice and total time as CPT code 93571 of 15 minutes. We disagree with the recommended work RVU of 1.50 for this CPT code because we do not believe that a reduction in work RVU from 1.80 to 1.50 is commensurate with the reduction in time for this service of five minutes. Using the building block methodology, we believe the work RVU for CPT code 93571 should be 1.35. We believe that a crosswalk to CPT code 61517 (Implantation of brain intracavitary chemotherapy agent (List separately in addition to CPT code for primary procedure)) with a work RVU of 1.38 is more appropriate because it has an identical intraservice and total time (15 minutes) as CPT code 93571, describes work that is similar, and is closer to the calculations for intraservice time ratio, total time ratio, and the building block method. Therefore, we are proposing a work RVU of 1.38 for CPT code 93571.

We are proposing the RUC-recommended work RVU for CPT code 93572 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel) of 1.00.

Both of these codes are facility-only procedures with no recommended direct PE inputs.

(53) Peripheral Artery Disease (PAD) Rehabilitation (CPT Code 93668)

During 2017, we issued a national coverage determination (NCD) for Medicare coverage of supervised exercise therapy (SET) for the treatment of peripheral artery disease (PAD). Previously, the service had been assigned noncovered status under the PFS. CPT code 93668 (Peripheral arterial disease (PAD) rehabilitation, per session) was payable before the end of CY 2017, retroactive to the effective date of the NCD (May 25, 2017), and for CY 2018, CMS made payment for Medicare-covered SET for the treatment of PAD,

consistent with the NCD, reported with CPT code 93668. We used the most recent RUC-recommended work and direct PE inputs and requested that the RUC review the service, which had not been reviewed since 2001, for direct PE inputs. The RUC is not recommending a work RVU for CPT code 93668 due to the belief that there is no physician work involved in this service. After reviewing this code, we are proposing a work RVU of 0.00 for CPT code 93668 and are proposing to continue valuing the code for PE only.

(54) Home Sleep Apnea Testing (CPT Codes 95800, 95801, and 95806)

CPT codes 95800 (Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time), 95801 (Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)), and 95806 (Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)) were flagged by the CPT Editorial Panel and reviewed at the October 2014 Relativity Assessment Workgroup meeting. Due to rapid growth in service volume, the RUC recommended that these services be reviewed after 2 more years of Medicare utilization data (2014 and 2015 data). These three codes were surveyed for the April 2017 RUC meeting and new recommendations for work and direct PE inputs were submitted to CMS.

For CPT code 95800, the RUC recommended a work RVU of 1.00 based on the survey 25th percentile value. We disagree with the recommended value and are proposing a work RVU of 0.85 based on a pair of crosswalk codes: CPT code 93281 (Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead pacemaker system) and CPT code 93260 (Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system). Both of these codes have a work RVU of 0.85, as well as having the same intraservice time of

15 minutes, similar total times to CPT code 95800, and recent review dates within the last few years.

In reviewing CPT code 95800, we noted that the recommended intraservice time is decreasing from 20 minutes to 15 minutes (25 percent reduction), and the recommended total time is decreasing from 50 minutes to 31 minutes (38 percent reduction); however, the RUC-recommended work RVU is only decreasing from 1.05 to 1.00, which is a reduction of less than 5 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 95800, we believe that it would be more accurate to propose a work RVU of 0.85 based on the aforementioned crosswalk codes to account for these decreases in the surveyed work time. We also note that in this case where the surveyed times are decreasing and the utilization of CPT code 95800 is increasingly significantly (quadrupling in the last 5 years), we have reason to believe that practitioners are becoming more efficient at performing the procedure, which, under the resource-based nature of the RVU system, lends further support for a reduction in the work RVU.

For CPT code 95801, the RUC proposed a work RVU of 1.00 again based on the survey 25th percentile. We disagree with the recommended value and we are again proposing a work RVU of 0.85 based on the same pair of crosswalk codes, CPT codes 93281 and 93260. We noted that CPT codes 95800 and 95801 had identical recommended work RVUs and identical recommended survey work times. Given that these two codes also have extremely similar work descriptors, we interpreted this to mean that the two codes could have the same work RVU, and therefore, we are proposing the same work RVU of 0.85 for both codes.

For CPT code 95806, the RUC recommended a work RVU of 1.08 based on a crosswalk to CPT code 95819 (Electroencephalogram (EEG); including recording awake and asleep). Although we disagree with the RUC-recommended work RVU of 1.08, we concur that the relative difference in work between CPT codes 95800 and 95801 and CPT code 95806 is equivalent to the recommended interval of 0.08 RVUs. Therefore, we are proposing a work RVU of 0.93 for CPT code 95806, based on the recommended interval of

0.08 additional RVUs above our proposed work RVU of 0.85 for CPT codes 95800 and 95801. We also note that CPT code 95806 is experiencing a similar change in the recommended work and time values comparable to CPT code 95800. The recommended intraservice time for CPT code 95806 is decreasing from 25 minutes to 15 minutes (40 percent), and the recommended total time is decreasing from 50 minutes to 31 minutes (38 percent); however, the recommended work RVU is only decreasing from 1.25 to 1.08, which is a reduction of only 14 percent. As we stated for CPT code 95800, we do not believe that decreases in work time must equate to a one-to-one or linear decrease in the valuation of work RVUs, but we do believe that these changes in surveyed work time suggest that practitioners are becoming more efficient at performing the procedure, and that it would be more accurate to maintain the recommended work interval with CPT codes 95800 and 95801 by proposing a work RVU of 0.93 for CPT code 95806.

We are not proposing any direct PE refinements for this code family.

(55) Neurostimulator Services (CPT Codes 95970, 95X83, 95X84, 95X85, and 95X86)

In October 2013, CPT code 95971 (Electronic analysis of implanted neurostimulator pulse generator system; simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming) was identified in the second iteration of the High Volume Growth screen. In January 2014, the RUC recommended that CPT codes 95971, 95972 (Electronic analysis of implanted neurostimulator pulse generator system; complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming) and 95974 (Electronic analysis of implanted neurostimulator pulse generator system; complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour) be referred to the CPT Editorial Panel to address the entire family regarding the time referenced in the CPT code descriptors. In June 2017, the CPT Editorial Panel revised CPT codes 95970, 95971, and 95972, deleted CPT codes 95974, 95975 (Electronic analysis of implanted neurostimulator pulse

generator system; complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour), 95978 (Electronic analysis of implanted neurostimulator pulse generator system, complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; first hour), and 95979 (Electronic analysis of implanted neurostimulator pulse generator system, complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; each additional 30 minutes after first hour) and created four new CPT codes for analysis and programming of implanted cranial nerve neurostimulator pulse generator, analysis, and programming of brain neurostimulator pulse generator systems and analysis of stored neurophysiology recording data.

The RUC recommended a work RVU of 0.45 for CPT code 95970 (Electronic analysis of implanted neurostimulator pulse generator/transmitter (*e.g.*, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve neurostimulator pulse generator/transmitter, without programming)), which is identical to the current work RVU for this CPT code. The descriptor for this CPT code has been modified slightly, but the specialty societies affirmed that the work itself has not changed. To justify its recommendation, the RUC provided two references: CPT code 62368 (Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming), with intraservice time of 15 minutes, total time of 27 minutes, and a work RVU of 0.67; and CPT code 99213 (Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; or Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/

or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family), with intraservice time of 15 minutes, total time of 23 minutes, and a work RVU of 0.97. We disagree with the RUC's recommendation because we do not believe that maintaining the work RVU, given a decrease of four minutes in total time, is appropriate. In addition, we note that the reference CPT codes chosen have much higher intraservice and total times than CPT code 95970, and also have higher work RVUs, making them poor comparisons. Instead, we identified a crosswalk to CPT code 95930 (Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report) with 10 minutes intraservice time, 14 minutes total time, and a work RVU of 0.35. Therefore, we are proposing a work RVU of 0.35 for CPT code 95970.

CPT code 95X83 (Electronic analysis of implanted neurostimulator pulse generator/transmitter (*e.g.*, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional) is a new CPT code replacing CPT code 95974 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.*, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour). The description of the work involved in furnishing CPT code 95X83 differs from that of the deleted CPT code in a few important ways, notably that the time parameter has been removed so that the CPT code no longer describes the first hour of programming. In addition, the new CPT code refers to simple rather than complex programming. Accordingly, the intraservice and total times for this CPT code are substantively different from those of the deleted CPT code. CPT code 95X83 has

an intraservice time of 11 minutes and a total time of 24 minutes, while CPT code 95974 has an intraservice time of 60 minutes and a total time of 110 minutes. The RUC recommended a work RVU of 0.95 for CPT code 95X83. The RUC's top reference CPT code as chosen by the RUC survey participants was CPT code 95816 (Electroencephalogram (EEG); including recording awake and drowsy), with an intraservice time of 15 minutes, 26 minutes total time, and a work RVU of 1.08. The RUC indicated that the service is similar, but somewhat more complex than CPT code 95X83. We disagree with the RUC's recommended work RVU for this CPT code because we do not believe that the large difference in time between the new CPT code and CPT code 95974 is reflected in the slightly smaller proportional decrease in work RVUs. The reduction in total time, from 110 minutes to 24 minutes is nearly 80 percent. However, the RUC's recommended work RVU reflects a reduction of just under 70 percent. We believe that a more appropriate crosswalk would be CPT code 76641 (Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete) with intraservice time of 12 minutes, total time of 22 minutes, and a work RVU of 0.73. Therefore, we are proposing a work RVU of 0.73 for CPT code 95X83.

CPT code 95X84 describes the same work as CPT code 95X83, but with complex rather than simple programming. The CPT Editorial Panel refers to simple programming of a neurostimulator pulse generator/transmitter as the adjustment of one to three parameter(s), while complex programming includes adjustment of more than three parameters. For purposes of applying the building block methodology and calculating intraservice and total time ratios, the RUC compared CPT code 94X84 with CPT code 95975 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.*, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour), which is being deleted by the CPT Editorial Panel. We believe that this was an inappropriate comparison since it is time based (first hour of programming) and is an add-on code. Instead we believe that the RUC

intended to compare CPT code 95X84 with CPT code 95974 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.*, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour), which has been recommended for deletion by the CPT Editorial Panel and is also the comparison for CPT code 95X83. The RUC recommended a work RVU of 1.19 for CPT code 95X84. The RUC disagreed with the two top reference services CPT code 99215 (Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; or Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family) and CPT code 99202 (Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; or straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family) and instead compared CPT code 95X84 to CPT code 99308 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; or Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or

family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 15 minutes are spent at the bedside and on the patient's facility floor or unit.) with total time of 31 minutes, intraservice time of 15 minutes, and a work RVU of 1.16; and CPT code 12013 (Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm), with total time of 27 minutes, intraservice time of 15 minutes, and a work RVU of 1.22. We disagree with the RUC's recommended work RVU of 1.19 for CPT code 95X84. Once the comparison CPT code is corrected to CPT code 95974, the reverse building block calculation indicates that a lower work RVU (close to 0.82) would be a better reflection of the work involved in furnishing this service. As an alternative to the RUC's recommendation, we added the difference in RUC-recommended work RVUs between CPT code 95X83 and 95X84 (0.24 RVUs) to the proposed work RVU of 0.73 for CPT code 95X83. Therefore, we propose a work RVU of 0.97 for CPT code 95X84.

CPT code 95X85 (Electronic analysis of implanted neurostimulator pulse generator/transmitter (*e.g.*, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, doe lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional) is the base for add-on CPT code 95X86 (Electronic analysis of implanted neurostimulator pulse generator/transmitter (*e.g.*, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, doe lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional), which is an add-on CPT code and can only be billed with CPT code 95X85. The RUC compared CPT code 95X85 with CPT code 95978 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.*, rate, pulse

amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; first hour), which the CPT Editorial Panel is recommending for deletion. The primary distinction between the new and old CPT codes is that the new CPT code describes the first 15 minutes of programming while the deleted CPT code describes up to one hour of programming. The RUC recommended a work RVU of 1.25 for CPT code 95X85 and a work RVU of 1.00 for CPT code 95X86. For CPT code 95X85, the RUC's recommendation is based on reference CPT codes 12013 (Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm), with total time of 27 minutes, intraservice time of 15 minutes, and a work RVU of 1.22; and CPT code 70470 (Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections) with 25 minutes of total time, 15 minutes of intraservice time, and a work RVU of 1.27. We disagree with the RUC's recommended work RVU for CPT code 95X85 because we do not believe that the reduction in work RVU reflects the change in time described by the CPT code. Using the reverse building block methodology, we estimate that a work RVU of nearer to 1.11 would be more appropriate. In addition, if we were to sum the RUC-recommended RVUs for a single hour of programming using one of the base CPT codes and three of the 15 minute follow-on CPT codes, 1 hour of programming would be valued at 4.25 work RVUs. This contrasts sharply from the work RVU of 3.50 for 1 hour of programming using the deleted CPT code 95978. We believe that a more appropriate valuation of the work involved in furnishing this service is reflected by a crosswalk to CPT code 93886 (Transcranial Doppler study of the intracranial arteries; complete study), with total time 27 minutes, intraservice time of 17 minutes, and a work RVU of 0.91. Therefore, we are proposing a work RVU of 0.91 for CPT code 95X85.

The RUC's recommended work RVU of 1.00 for CPT code 95X86 is based on the key reference service CPT code 64645 (Chemodenervation of one extremity; each additional extremity, 5 or more muscles), which has total time of 26 minutes, intraservice time of 25 minutes, and a work RVU 1.39. This new CPT code is replacing CPT code 95978 (Electronic analysis of implanted

neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; first hour), which is being deleted by the CPT Editorial Panel. If we add the incremental difference between CPT codes 95X85 and 95X86 to the proposed value for the base CPT code (95X85, work RVU = 0.91), we estimate that this add-on CPT code should have a work RVU of 0.75. The building block methodology results in a recommendation of a slightly higher work RVU of 0.82. We are proposing a work RVU of 0.80 for CPT code 95X86, which falls between the calculated value using incremental differences and the calculation from the reverse building block, and is supported by a crosswalk to CPT code 51797 (Voiding pressure studies, intra-abdominal (*i.e.*, rectal, gastric, intraperitoneal)), which is an add-on CPT code with identical total and intraservice times (15 minutes) as CPT code 95X86.

We are not proposing any direct PE refinements for this code family.

(56) Psychological and Neuropsychological Testing (CPT Codes 96105, 96110, 96116, 96125, 96127, 963X0, 963X1, 963X2, 963X3, 963X4, 963X5, 963X6, 963X7, 963X8, 963X9, 96X10, 96X11, 96X12)

In CY 2016, the Psychological and Neuropsychological Testing family of codes were identified as potentially misvalued using a high expenditure services screen across specialties with Medicare allowed charges of \$10 million or more. The entire family of codes was referred to the CPT Editorial Panel to be revised, as the testing practices had been significantly altered by the growth and availability of technology, leading to confusion about how to report the codes. In June 2017, the CPT Editorial Panel revised five existing codes, added 13 codes to provide better description of psychological and neuropsychological testing, and deleted CPT codes 96101, 96102, 96103, 96111, 96118, 96119, and 96120. The RUC and HCPAC submitted recommendations for the 13 new codes and for the existing CPT codes 96105, 96110, 96116, 96125, and 96127.

We are proposing the RUC- and HCPAC-recommended work RVUs for several of the CPT codes in this family: A work RVU of 1.75 for CPT code 96105; a work RVU of 1.86 for CPT code 96116; a work RVU of 1.70 for CPT code 96125; a work RVU of 1.71 for CPT code

963X2; a work RVU of 0.55 for CPT code 963X7; a work RVU of 0.46 for CPT code 963X8; and a work RVU of 0.51 for CPT code 96X11. CPT codes 96110, 96127, 963X9, 96X10, and 96X12 were valued by the RUC for PE only.

This code family contains a subset of codes that describe psychological and neuropsychological testing administration and evaluation, not including assessment of aphasia, developmental screening, or developmental testing. The CPT Editorial Panel's recommended coding for this subset of services consists of seven new codes: Two that describe either psychological or neuropsychological testing when administered by physicians or other qualified health professionals (CPT codes 963X7 and 963X8), and two for either type of testing when administered by technicians (CPT codes 963X9 and 96X10); and four new codes that describe testing evaluation by physicians or other qualified health care professionals (CPT codes 963X3–963X6). This new coding effectively unbundles codes that currently report the full course of testing into separate codes for testing administration (CPT codes 963X7, 963X8, 963X9, and 96X10) and evaluation (CPT Codes 963X3, 963X4, and 963X5). According to a stakeholder that represents the psychologist and neuropsychologist community, this new coding will result in significant reductions in payment for these services due to the unbundling of the testing codes into codes for physician-administered tests and technician-administered tests. The stakeholder asserts that because the new coding includes testing codes with zero work RVUs for the technician administered tests and the work RVUs are lower than they believe to be accurate, this new valuation would ignore the clinical evaluation and decision making performed by the physician or other qualified health professional during the course of testing administration and evaluation. Furthermore, the net result of the code valuations for these new codes is a reduction in the overall work RVUs for this family of codes. In other words, the stakeholder's analysis found that the RUC recommendations result in a reduction in total work RVUs, even though the actual physician work of a testing battery has not changed.

In the interest of payment stability for these high-volume services, we are proposing to implement work RVUs for this code family, which would eliminate the approximately 2 percent reduction in work spending. We are proposing to achieve work neutrality for this code

family by scaling the work RVUs upward from the RUC-recommended values so that the size of the pool of work RVUs would be essentially unchanged for this family of services. Therefore, we are proposing: A work RVU of 2.56 for CPT code 963X0, rather than the RUC recommended work RVU of 2.50; a work RVU of 1.16 for CPT code 963X1, rather than the RUC-recommended work RVU of 1.10; a work RVU of 2.56 for CPT code 963X3, rather than the RUC-recommended work RVU of 2.50; a work RVU of 1.96 for CPT code 963X4, rather than the RUC-recommended work RVU of 1.90; a work RVU of 2.56 for CPT code 963X5, rather than the RUC-recommended work RVU of 2.50; and a work RVU of 1.96 for CPT code 963X6, rather than the RUC-recommended work RVU of 1.90. We see no evidence that the typical practice for these services has changed to merit a reduction in valuation of professional services.

The RUC made several revisions to the recommended direct PE inputs for the administration codes from their respective predecessor codes, including revisions to quantities of testing forms. For the supply item, “psych testing forms, average” there is a quantity of 0.10 in the predecessor CPT code 96101, and a quantity of 0.33 in the predecessor CPT code 96102. For the supply item “neurobehavioral status forms, average,” there is a quantity of 1.0 in the predecessor CPT code 96118 and a quantity of 0.30 for predecessor CPT code 96119, and for the supply item “aphasia assessment forms, average,” there is a quantity of 1.0 in the predecessor CPT code 96118 and a quantity of 0.30 in predecessor CPT code 96119. The RUC recommendation does not include any forms for CPT codes 963X5 and 963X6. The RUC has replaced the corresponding predecessor supply items with new items “WAIS–IV Record Form,” “WAIS–IV Response Booklet #1,” and “WAIS–IV Response Booklet #2,” and assigned quantities of 0.165 for each of these new supply items for CPT codes 963X7–96X10. In our analysis, we find that the RUC-recommended PE refinements contributes significantly to the reduction in the overall payment for this code family. We see no compelling evidence that the quantities of testing forms used in a typical course of testing would have reduced dramatically and, in the interest of payment stability, we are proposing to refine the direct PE inputs for CPT codes 963X5–96X10 by including 1.0 quantity each of the supply items “WAIS–IV Record Form,” “WAIS–IV Response Booklet #1,” and

“WAIS–IV Response Booklet #2.” We believe that a typical course of testing would involve use of one booklet for each of the relevant codes. In addition, these proposed refinements would largely mitigate potentially destabilizing payment reductions for these services. We are seeking comment on our proposed work RVUs and proposed PE refinements for this family of services.

For the direct PE inputs, we are proposing to remove the equipment time for the CANTAB Mobile (ED055) equipment item from CPT code 96X12. This item was listed at different points in the recommendations as a supply item with a cost of \$28 per assessment and as an equipment item for a software license with a cost of \$2,800 that could be used for up to 100 assessments. We are unclear as to how the CANTAB Mobile would typically be used in this procedure, and we are proposing to remove the equipment time pending the submission of more data about the item. We are seeking additional information about the use of this item and how it should best be included into the PE methodology. We are also interested in information as to whether the submitted invoice refers to the cost of the mobile device itself, or the cost of user licenses for the mobile device, which was unclear from the information submitted with the recommendations.

(57) Electrocorticography (CPT Code 96X00)

CPT Code 95829 is used for Electrocorticogram performed at the time of surgery; however, a new code was needed to account for this non-face-to-face service for the review of a month's worth or more of stored data. CPT code 96X00 (Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days) is a new code approved at the September 2017 CPT Editorial Panel Meeting to describe this service.

We disagree with the RUC-recommended work RVU of 2.30 for CPT code 96X00 and are proposing a work RVU of 1.98 based on a direct crosswalk to the top reference, CPT code 95957 (Digital analysis of electroencephalogram (EEG) (*e.g.*, for epileptic spike analysis)). This is a recently-reviewed code with the same intraservice time of 30 minutes and a total time only 2 minutes lower than CPT code 96X00. We agree with the survey respondents that CPT code 95957 is an accurate valuation for this new code, and due to the clinically similar nature of the two procedures and their near-identical time values, we

are proposing to value both of them at the same work RVU of 1.98.

The RUC did not recommend, and we did not propose, any direct PE inputs for CPT code 96X00.

(58) Chronic Care Remote Physiologic Monitoring (CPT Codes 990X0, 990X1, and 994X9)

In the CY 2018 PFS final rule, we finalized separate payment for CPT code 99091 (Collection and interpretation of physiologic data (*e.g.*, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time) (82 FR 53014). In that rule, we indicated that there would be new coding describing remote monitoring forthcoming from the CPT Editorial Panel and the RUC (82 FR 53014). In September 2017, the CPT Editorial Panel revised one code and created three new codes to describe remote physiologic monitoring and management and the RUC provided valuation recommendations through our standard rulemaking process.

CPT codes 990X0 (Remote monitoring of physiologic parameter(s) (*e.g.*, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment) and 990X1 (Remote monitoring of physiologic parameter(s) (*e.g.*, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days) are both PE-only codes. We are proposing the RUC-recommended work RVU of 0.61 for CPT code 994X9 (Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month).

For the direct PE inputs, we are proposing to accept the RUC-recommended direct PE inputs for CPT code 990X0 and to remove the “Monthly cellular and licensing service fee” supply from CPT code 990X1. We do not believe that these licensing fees would be allocated to the use of an individual patient for an individual service, and instead believe they can be better understood as forms of indirect costs similar to office rent or administrative expenses. Therefore, we are proposing to remove this supply input as a form of indirect PE. We are

proposing the direct PE inputs for CPT code 994X9 without refinement.

(59) Interprofessional Internet Consultation (CPT Codes 994X6, 994X0, 99446, 99447, 99448, and 99449)

In September 2017, the CPT Editorial Panel revised four codes and created two codes to describe interprofessional telephone/internet/electronic medical record consultation services. CPT codes 99446 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5–10 minutes of medical consultative discussion and review), 99447 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11–20 minutes of medical consultative discussion and review), 99448 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21–30 minutes of medical consultative discussion and review), and 99449 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review) describe assessment and management services in which a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a physician with specific specialty expertise to assist with the diagnosis and/or management of the patient's problem without the need for the face-to-face interaction between the patient and the consultant. These CPT codes are currently assigned a procedure status of B (bundled) and are not separately payable under Medicare. The CPT Editorial Panel revised these codes to include electronic health record consultations, and the RUC reaffirmed the work RVUs it had previously submitted for these codes. We reevaluated the submitted recommendations and, in light of changes in medical practice and technology, we are proposing to change the procedure status for CPT codes 99446, 99447, 99448, and 99449 from B

(bundled) to A (active). We are also proposing the RUC re-affirmed work RVUs of 0.35 for CPT code 99446, 0.70 for CPT code 99447, 1.05 for CPT code 99448, and 1.40 for CPT code 99449.

The CPT Editorial Panel also created two new codes, CPT code 994X0 (Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes) and CPT code 994X6 (Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time). The RUC-recommended work RVUs are 0.50 for CPT code 994X0 and 0.70 for 994X6. Since the CPT code for the treating/requesting physician or qualified healthcare professional and the CPT code for the consultative physician have similar intraservice times, we believe that these CPT codes should have equal values for work. Therefore, we are proposing a work RVU of 0.50 for both CPT codes 994X0 and 994X6.

We welcome comments on this proposal. We also direct readers to section II.D. of this proposed rule, which includes additional detail regarding our proposed policies for modernizing Medicare physician payment by recognizing communication technology-based services.

There are no recommended direct PE inputs for the codes in this family.

(60) Chronic Care Management Services (CPT Code 994X7)

In February 2017, the CPT Editorial Panel created a new code to describe at least 30 minutes of chronic care management services performed personally by the physician or qualified health care professional over one calendar month. CMS began making separate payment for CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored) in CY 2015 (79 FR 67715). CPT code 99490 describes 20 minutes of clinical staff

time spent on care management services for patients with 2 or more chronic conditions. CPT code 99490 also includes 15 minutes of physician time for supervision of clinical staff. For CY 2019, the CPT Editorial Panel created CPT code 994X7 (Chronic care management services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored) to describe situations when the billing practitioner is doing the care coordination work that is attributed to clinical staff in CPT code 99490. For CPT code 994X7, the RUC recommended a work RVU of 1.45 for 30 minutes of physician time. We believe this work RVU overvalues the resource costs associated with the physician performing the same care coordination activities that are performed by clinical staff in the service described by CPT code 99490.

Additionally, this valuation of the work is higher than that of CPT code 99487 (Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or substantial revision of a comprehensive care plan, moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month), which includes 60 minutes of clinical staff time, creating a rank order anomaly within the family of codes if we were to accept the RUC-recommended value.

CPT code 99490 has a work RVU of 0.61 for 15 minutes of physician time. Therefore, as CPT code 994X7 describes 30 minutes of physician time, we are proposing a work RVU of 1.22, which is double the work RVU of CPT code 99490.

We are not proposing any direct PE refinements for this code family.

(61) Diabetes Management Training (HCPCS Codes G0108 and G0109)

HCPCS codes G0108 (Diabetes outpatient self-management training services, individual, per 30 minutes) and G0109 (Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes) were identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. For CY 2019, we are proposing the HCPAC-recommended work RVU of 0.90 for HCPCS code G0108 and the HCPAC-recommended work RVU of 0.25 for HCPCS code G0109.

For the direct PE inputs, we note that there is a significant disparity between the specialty recommendation and the final recommendation submitted by the HCPAC. We are concerned about the significant decreases in direct PE inputs in the final recommendation when compared to the current makeup of the two codes. The final HCPAC recommendation removed a series of different syringes and the patient education booklet that currently accompanies the procedure. We believe that injection training is part of these services and that the supplies associated with that training would typically be included in the procedures. Due to these concerns, we are proposing to maintain the current direct PE inputs for HCPCS codes G0108 and G0109. Therefore, we will not add the new supply item "20x30 inch self-stick easel pad, white, 30 sheets/pad" (SK129) to HCPCS code G0109, as it is not a current supply for HCPCS code G0109; however, we are proposing to accept the submitted invoice price and to add the supply to our direct PE database.

(62) External Counterpulsation (HCPCS Code G0166)

HCPCS code G0166 (External counterpulsation, per treatment session) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. The RUC is not recommending a work RVU for HCPCS code G0166 due to the belief that there is no physician work involved in this service. After reviewing this code, we are proposing a work RVU of 0.00 for HCPCS code G0166, and are proposing to make the code valued for PE only.

For the direct PE inputs, we are proposing to refine the equipment times in accordance with our standard equipment time formulas.

(63) Wound Closure by Adhesive
(HCPCS Code G0168)

HCPCS code G0168 (Wound closure utilizing tissue adhesive(s) only) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, the RUC recommended a work RVU of 0.45 based on maintaining the current work RVU.

We disagree with the recommended value and we are proposing a work RVU of 0.31 for HCPCS code G0168 based on a direct crosswalk to CPT code 93293 (Transtelephonic rhythm strip pacemaker evaluation(s) single, dual, or multiple lead pacemaker system, includes recording with and without magnet application with analysis, review and report(s) by a physician or other qualified health care professional, up to 90 days). CPT code 93293 is a recently-reviewed code with the same 5 minutes of intraservice time and 1 fewer minute of total time. In reviewing HCPCS code G0168, the recommendations stated that the work involved in the service had not changed even though the surveyed intraservice time was decreasing by 50 percent, from 10 minutes to 5 minutes. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In the case of HCPCS code G0168, we believe that it would be more accurate to propose a work RVU of 0.31 based on the aforementioned crosswalk to CPT code 93293 to account for these decreases in the surveyed work time. Maintaining the current work RVU of 0.45 despite a 50 percent decrease in the surveyed intraservice time would result in a significant increase in the intensity of HCPCS code G0168, and we have no reason to believe that the procedure has increased in intensity since the last time that it was valued.

For the direct PE inputs, we are proposing to refine the equipment times in accordance with our standard equipment time formulas.

(64) Removal of Impacted Cerumen
(HCPCS Code G0268)

HCPCS code G0268 (Removal of impacted cerumen (one or both ears) by physician on same date of service as

audiologic function testing) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we are proposing the RUC-recommended work RVU of 0.61 for HCPCS code G0268.

For the direct PE inputs, we are proposing to remove the clinical labor time for the “Clean surgical instrument package” (CA026) activity. There is no surgical instrument pack included in the recommended equipment for HCPCS code G0268, and this code already includes the standard 3 minutes allocated for cleaning the room and equipment. In addition, all of the instruments used in the procedure appear to be disposable supplies that would not require cleaning since they would only be used a single time.

(65) Structured Assessment, Brief Intervention, and Referral to Treatment for Substance Use Disorders (HCPCS Codes G0396, G0397, and G5BR1)

In response to the Request for Information in the CY 2018 PFS proposed rule (82 FR 34172), commenters requested that CMS pay separately for assessment and referral related to substance use disorders. In the CY 2008 PFS final rule (72 FR 66371), we created two G-codes to allow for appropriate Medicare reporting and payment for alcohol and substance abuse assessment and intervention services that are not provided as screening services, but that are performed in the context of the diagnosis or treatment of illness or injury. The codes are HCPCS code G0396 (Alcohol and/or substance (other than tobacco) abuse structured assessment (*e.g.*, AUDIT, DAST) and brief intervention, 15 to 30 minutes)) and HCPCS code G0397 (Alcohol and/or substance (other than tobacco) abuse structured assessment (*e.g.*, AUDIT, DAST) and intervention greater than 30 minutes)). In 2008, we instructed Medicare contractors to pay for these codes only when the services were considered reasonable and necessary.

Given the ongoing opioid epidemic and the current needs of the Medicare population, we expect that these services would often be reasonable and necessary. However, the utilization for these services is relatively low, which we believe is in part due to the service-specific documentation requirements for these codes (the current requirements can be found here: [https://](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/SBIRT_Factsheet_ICN904084.pdf)

www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/SBIRT_Factsheet_ICN904084.pdf). We believe that removing the additional documentation requirements will also ease the administrative burden on providers. Therefore, for CY 2019, we are proposing to eliminate the service-specific documentation requirements for HCPCS codes G0397 and G0398. We welcome comments on our proposal to change the documentation requirements for these codes.

Additionally, we are proposing to create a third HCPCS code, G5BR1, with a lower time threshold in order to accurately account for the resource costs when practitioners furnish these services, but do not meet the requirements of the existing codes. The proposed code descriptor is: Alcohol and/or substance (other than tobacco) abuse structured assessment (*e.g.*, AUDIT, DAST), and brief intervention, 5–14 minutes. We are proposing a work RVU of 0.33, based on the intraservice time ratio between HCPCS codes G0396 and G0397. We welcome comments on this code descriptor and proposed valuation for HCPCS code G5BR1.

(66) Prolonged Services (HCPCS Code GPRO1)

CPT codes 99354 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)) and 99355 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)) describe additional time spent face-to-face with a patient. Stakeholders claim that the threshold of 60 minutes for CPT code 99354 is difficult to meet and is an impediment to billing these codes. In response to stakeholder feedback and as part of our proposal as discussed in section II.I. of this proposed rule to implement a single PFS rate for E/M visit levels 2–5 while maintaining payment stability across the specialties, we are proposing HCPCS code GPRO1 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the

office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)), which could be billed with any level of E/M code. We note that we do not propose to make any changes to CPT codes 99354 and 99355, which could still be billed, as needed, when their time thresholds and all other requirements are met. We are proposing a work RVU of 1.17, which is equal to half of the work RVU assigned to CPT code 99354. Additionally, we are proposing direct PE inputs for HCPCS code GPRO1 that are equal to one half of the values assigned to CPT code 99354, which can be found in the Direct PE Inputs public use file for this proposed rule.

(67) Remote Pre-Recorded Services (HCPCS Code GRAS1)

For CY 2019, we are proposing to make separate payment for remote services when a physician uses pre-recorded video and/or images submitted by a patient in order to evaluate a patient's condition through new HCPCS G-code GRAS1 (Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment). We are proposing to value this service by a direct crosswalk to CPT code 93793 (Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed), as we believe the work described is similar in kind and intensity to the work performed as part of HCPCS code GRAS1. Therefore, we are proposing a work RVU of 0.18, preservice time of 3 minutes, intraservice time of 4 minutes, and post service time of 2 minutes. We are also proposing to add 6 minutes of clinical labor (L037D) in the service period. We are seeking comment on the code descriptor and valuation for HCPCS code GRAS1. We direct readers to section II.D. of this proposed rule, which includes additional detail regarding our proposed policies for modernizing Medicare physician payment by recognizing communication technology-based services.

(68) Brief Communication Technology-Based Service, e.g., Virtual Check-in (HCPCS Code GVCI1)

We are proposing to create a G-code, HCPCS code GVCI1 (Brief communication technology based service, e.g. virtual check-in, by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion) to facilitate payment for these brief communication technology-based services. We propose to base the code descriptor and valuation for HCPCS code GVCI1 on existing CPT code 99441 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion), which is currently not separately payable under the PFS. As CPT code 99441 only describes telephone calls, we are proposing to create a new HCPCS code GVCI1 to encompass a broader array of communication modalities. We do, however, believe that the resource assumptions for CPT code 99441 would accurately account for the costs associated with providing the proposed virtual check-in service, regardless of the technology. We are proposing a work RVU of 0.25, based on a direct crosswalk to CPT code 99441. For the direct PE inputs for HCPCS code GVCI1, we are also proposing the direct PE inputs assigned to CPT code 99441. Given the breadth of technologies that could be described as telecommunications, we look forward to receiving public comments and working with the CPT Editorial Panel and the RUC to evaluate whether separate coding and payment is needed to account for differentiation between communication modalities. We are seeking comment on the code descriptor, as well as the proposed valuation for HCPCS code GVCI1. We direct readers to section II.D. of this proposed rule, which includes additional detail regarding our proposed policies for modernizing Medicare physician payment by recognizing

communication technology-based services.

(69) Visit Complexity Inherent to Certain Specialist Visits (HCPCS Code GCG0X)

We are proposing to create a HCPCS G-code to be reported with an E/M service to describe the additional resource costs for specialties for whom E/M visit codes make up a large percentage of their total allowed charges and who we believe primarily bill level 4 and level 5 visits. The treatment approaches for these specialties generally do not have separate coding and are generally reported using the E/M visit codes. We are proposing to create HCPCS code, GCG0X (Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit)). We are proposing a valuation for HCPCS code GCG0X based on a crosswalk to 75 percent of the work RVU and time of CPT code 90785 (Interactive complexity), which would result in a proposed work RVU of 0.25 and a physician time of 8.25 minutes for HCPCS code GCG0X. CPT code 90785 has no direct PE inputs. Interactive complexity is an add-on code that may be billed when a psychotherapy or psychiatric service requires more work due to the complexity of the patient. We believe that this work RVU and physician time would be an accurate representation of the additional work associated with the higher level complex visits. For further discussion of proposals relating to this code, see section II.I of this proposed rule. We are seeking comment on the code descriptor, as well as the proposed valuation for HCPCS code GCG0X.

(70) Visit Complexity Inherent to Primary Care Services (HCPCS Code GPC1X)

We are proposing to create a HCPCS G-code for primary care services, GPC1X (Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an evaluation and management visit)). This code describes furnishing a visit to a new or existing patient, and can include aspects of care management, counseling, or treatment of acute or chronic

conditions not accounted for by other coding. HCPCS code GPC1X would be billed in addition to the E/M visit code when the visit involved primary care-focused services. We are proposing a work RVU of 0.07, physician time of 1.75 minutes. This proposed valuation accounts for the additional work resource costs associated with furnishing primary care that distinguishes E/M primary care visits from other types of E/M visits and maintains work budget neutrality across the office/outpatient E/M code set. For further discussion of proposals relating to this code, see section II.I of this proposed rule. We are seeking comment on the code descriptor, as well as the proposed valuation for HCPCS code GPC1X.

(71) Podiatric Evaluation and Management Services (HCPCS Codes GPD0X and GPD1X)

We are proposing to create two HCPCS G-codes, HCPCS codes GPD0X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, new patient) and GPD1X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, established patient), to describe podiatric evaluation and management services. We are proposing a work RVU of 1.36, a physician time of 28.19 minutes, and direct costs summing to \$21.29 for HCPCS code GPD0X, and a work RVU of 0.85, physician time of 21.73 minutes, and direct costs summing to \$15.87 for HCPCS code GPD1X. These values are based on the average rate for CPT codes 99201–99203 and CPT codes 99211–99212 respectively, weighted by podiatric volume. For further discussion of proposals relating to these codes, see section II.I of this proposed rule.

(72) Comment Solicitation on Superficial Radiation Treatment Planning and Management

In the CY 2015 PFS final rule with comment period (79 FR 67666–67667), we noted that changes to the CPT prefatory language limited the codes that could be reported when describing services associated with superficial radiation treatment (SRT) delivery, described by CPT code 77401 (radiation treatment delivery, superficial and/or ortho voltage, per day). The changes effectively meant that many other related services were bundled with CPT code 77401, instead of being separately reported. For example, CPT guidance clarified that certain codes used to describe clinical treatment planning, treatment devices, isodose planning,

physics consultation, and radiation treatment management cannot be reported when furnished in association with SRT. Stakeholders informed us that these changes to the CPT prefatory language prevented them from billing Medicare for codes that were previously frequently billed with CPT code 77401. We solicited comments as to whether the revised bundled coding for SRT allowed for accurate reporting of the associated services. In the CY 2016 PFS final rule with comment period (80 FR 70955), we noted that the RUC did not review the inputs for SRT procedures, and therefore, did not assess whether changes in valuation were appropriate in light of the bundling of associated services. In addition, we solicited recommendations from stakeholders regarding whether it would be appropriate to add physician work for this service, even though physician work is not included in other radiation treatment services. In the CY 2018 PFS proposed rule (82 FR 34012) and the CY 2018 PFS final rule (82 FR 53082), we noted that the 2016 National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services states that radiation oncology services may not be separately reported with E/M codes. While this NCCI edit is no longer active stakeholders have stated that MACs have denied claims for E/M services associated with SRT based on the NCCI policy manual language. According to stakeholders, the bundling of SRT with associated services, as well as coding confusion regarding the appropriate use of E/M coding to report associated physician work, meant that practitioners were not being paid appropriately for planning and treatment management associated with furnishing SRT. Due to these concerns regarding reporting of services associated with SRT, in the CY 2018 PFS proposed rule (82 FR 34012–34013), we proposed to make separate payment for the professional planning and management associated with SRT using HCPCS code GRRR1 (Superficial radiation treatment planning and management related services, including but not limited to, when performed, clinical treatment planning (for example, 77261, 77262, 77263), therapeutic radiology simulation-aided field setting (for example, 77280, 77285, 77290, 77293), basic radiation dosimetry calculation (for example, 77300), treatment devices (for example, 77332, 77333, 77334), isodose planning (for example, 77306, 77307, 77316, 77317, 77318), radiation treatment management (for example, 77427, 77431, 77432, 77435, 77469, 77470, 77499), and associated E/M per course of treatment).

We proposed that this code would describe the range of professional services associated with a course of SRT, including services similar to those not otherwise separately reportable under CPT guidance. Furthermore, we proposed that this code would have included several inputs associated with related professional services such as treatment planning, treatment devices, and treatment management. Many commenters did not support our proposal to make separate payment for HCPCS code GRRR1 for CY 2018, stating that our proposed valuation of HCPCS code GRRR1 would represent a significant payment reduction for the associated services as compared with the list of services that they could previously bill in association with SRT. Commenters voiced concern that the proposed coding would inhibit access to care and discourage the use of SRT as a non-surgical alternative to Mohs surgery. We received comments recommending a variety of potential coding solutions and found that there was not general agreement among commenters about a preferred alternative. In the CY 2018 PFS final rule (82 FR 53081–53083), we solicited further comment, and stated that we would continue our dialogue with stakeholders to address appropriate coding and payment for professional services associated with SRT.

Given stakeholder feedback that we have continued to receive following the publication of the CY 2018 PFS final rule, we continue to believe that there are potential coding gaps for SRT-related professional services. We generally rely on the CPT process to determine coding specificity, and we believe that deferring to this process in addressing potential coding gaps is generally preferable. As our previous attempt at designing a coding solution in the CY 2018 PFS proposed rule did not gain stakeholder consensus, and given that there were various, in some cases diverging, suggestions on a coding solution from stakeholders, we are not proposing changes relating to SRT coding, SRT-related professional codes, or payment policies for CY 2019. However, we are seeking comment on the possibility of creating multiple G-codes specific to services associated with SRT, as was suggested by one stakeholder following the CY 2018 PFS final rule. These codes would be used separately to report services including SRT planning, initial patient simulation visit, treatment device design and construction associated with SRT, SRT management, and medical physics consultation. We are seeking comment

on whether we should create such G codes to separately report each of the services described above, mirroring the coding of other types of radiation treatment delivery. For instance, HCPCS code G6003 (Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: Up to 5 mev) is used to report radiation treatment delivery, while associated professional services are billed with codes such as CPT codes 77427 (Radiation treatment management, 5 treatments), 77261 (Therapeutic radiology treatment planning; simple), 77332 (Treatment devices, design and construction; simple (simple block, simple bolus), and 77300 (Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity

factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician). We are interested in public comment on whether it would be appropriate to create separate codes for professional services associated with SRT in a coding structure parallel to radiation treatment delivery services such as HCPCS code G6003. We are seeking comment on creating these codes for inclusion in this update of the PFS. We are also interested in whether such codes should be contractor priced for CY 2019. We would consider contractor pricing such codes for CY 2019 because we believe that the preferable method to develop new coding is with multi-specialty input through the CPT and RUC process, and we prefer to defer nationally pricing

such codes pending input from the CPT Editorial Panel and the RUC process to assist in determining the appropriate level of coding specificity for SRT-related professional services. Based on stakeholder feedback, we continue to believe there may be a coding gap for these services, and therefore, we are soliciting comment on whether we should create these G codes and allow them to be contractor priced for CY 2019. This would be an interim approach for addressing the potential coding gap until the CPT Editorial Panel and the RUC can address coding for SRT and SRT-related professional services, giving the CPT Editorial Panel and the RUC an opportunity to develop a coding solution that could be addressed in future rulemaking.

TABLE 13—CY 2019 PROPOSED WORK RVUS FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
03X0T	Electroretinography (ERG) with interpretation and report, pattern (PERG).	NEW	C	0.40	No.
10021	Fine needle aspiration biopsy; without imaging guidance; first lesion.	1.27	1.20	1.03	No.
10X11	Fine needle aspiration biopsy; without imaging guidance; each additional lesion.	NEW	0.80	0.80	No.
10X12	Fine needle aspiration biopsy, including ultrasound guidance; first lesion.	NEW	1.63	1.46	No.
10X13	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion.	NEW	1.00	1.00	No.
10X14	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion.	NEW	1.81	1.81	No.
10X15	Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion.	NEW	1.18	1.18	No.
10X16	Fine needle aspiration biopsy, including CT guidance; first lesion.	NEW	2.43	2.26	No.
10X17	Fine needle aspiration biopsy, including CT guidance; each additional lesion.	NEW	1.65	1.65	No.
10X18	Fine needle aspiration biopsy, including MR guidance; first lesion.	NEW	C	C	No.
10X19	Fine needle aspiration biopsy, including MR guidance; each additional lesion.	NEW	C	C	No.
11755	Biopsy of nail unit (e.g., plate, bed, matrix, hyponychium, proximal and lateral nail folds).	1.31	1.25	1.08	No.
11X02	Tangential biopsy of skin, (e.g., shave, scoop, saucerize, curette), single lesion.	NEW	0.66	0.66	No.
11X03	Tangential biopsy of skin, (e.g., shave, scoop, saucerize, curette), each separate/additional lesion.	NEW	0.38	0.29	No.
11X04	Punch biopsy of skin, (including simple closure when performed), single lesion.	NEW	0.83	0.83	No.
11X05	Punch biopsy of skin, (including simple closure when performed), each separate/additional lesion.	NEW	0.45	0.45	No.
11X06	Incisional biopsy of skin (e.g., wedge), (including simple closure when performed), single lesion.	NEW	1.01	1.01	No.
11X07	Incisional biopsy of skin (e.g., wedge), (including simple closure when performed), each separate/additional lesion.	NEW	0.54	0.54	No.
20551	Injection(s); single tendon origin/insertion	0.75	0.75	0.75	No.
209X3	Allograft, includes templating, cutting, placement and internal fixation when performed; osteoarticular, including articular surface and contiguous bone.	NEW	13.01	13.01	No.
209X4	Allograft, includes templating, cutting, placement and internal fixation when performed; hemicortical intercalary, partial (i.e., hemicylindrical).	NEW	11.94	11.94	No.

TABLE 13—CY 2019 PROPOSED WORK RVUS FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
209X5	Allograft, includes templating, cutting, placement and internal fixation when performed; intercalary, complete (i.e., cylindrical).	NEW	13.00	13.00	No.
27X69	Injection procedure for contrast knee arthrography or contrast enhanced CT/MRI knee arthrography.	NEW	0.96	0.77	No.
29105	Application of long arm splint (shoulder to hand)	0.87	0.80	0.80	No.
29540	Strapping; ankle and/or foot	0.39	0.39	0.39	No.
29550	Strapping; toes	0.25	0.25	0.25	No.
31623	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with brushing or protected brushings.	2.63	2.63	2.63	No.
31624	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial alveolar lavage.	2.63	2.63	2.63	No.
332X0	Transcatheter implantation of wireless pulmonary artery pressure sensor for long term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed.	NEW	6.00	6.00	No.
332X5	Insertion, subcutaneous cardiac rhythm monitor, including programming.	NEW	1.53	1.53	No.
332X6	Removal, subcutaneous cardiac rhythm monitor	NEW	1.50	1.50	No.
335X1	Replacement, aortic valve; by translocation of autologous pulmonary valve and transventricular aortic annulus enlargement of the left ventricular outflow tract with valved conduit replacement of pulmonary valve (Ross-Konno procedure).	NEW	64.00	64.00	No.
33X01	Aortic hemiarach graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion.	NEW	19.74	19.74	No.
33X05	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed.	NEW	8.77	7.80	No.
33X06	Transcatheter removal of permanent leadless pacemaker, right ventricular.	NEW	9.56	8.59	No.
36568	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; younger than 5 years of age.	1.67	2.11	2.11	No.
36569	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; age 5 years or older.	1.70	1.90	1.90	No.
36584	Replacement, complete, of a peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, through same venous access, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the replacement.	1.20	1.47	1.20	No.
36X72	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; younger than 5 years of age.	NEW	2.00	1.82	No.
36X73	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older.	NEW	1.90	1.70	No.
3853X	Biopsy or excision of lymph node(s); open, inguofemoral node(s).	NEW	6.74	6.74	No.
38792	Injection procedure; radioactive tracer for identification of sentinel node.	0.52	0.65	0.65	No.

TABLE 13—CY 2019 PROPOSED WORK RVUS FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
43X63	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; not requiring revision of gastrostomy tract.	NEW	0.75	0.75	No.
43X64	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract.	NEW	1.41	1.41	No.
45300	Proctosigmoidoscopy, rigid; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure).	0.80	0.80	0.80	No.
46500	Injection of sclerosing solution, hemorrhoids	1.42	2.00	1.74	No.
49422	Removal of tunneled intraperitoneal catheter	6.29	4.00	4.00	No.
50X39	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, as well as post procedure tube placement, when performed.	NEW	3.37	2.78	No.
50X40	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, as well as post procedure tube placement, when performed; including new access into the renal collecting system.	NEW	5.44	4.83	Yes.
52334	Cystourethroscopy with insertion of ureteral guide wire through kidney to establish a percutaneous nephrostomy, retrograde.	4.82	3.37	3.37	No.
53850	Transurethral destruction of prostate tissue; by microwave thermotherapy.	10.08	5.42	5.42	No.
53852	Transurethral destruction of prostate tissue; by radio-frequency thermotherapy.	10.83	5.93	5.93	No.
538X3	Transurethral destruction of prostate tissue; by radio-frequency generated water vapor thermotherapy.	NEW	5.93	5.70	No.
57150	Irrigation of vagina and/or application of medicament for treatment of bacterial, parasitic, or fungoid disease.	0.55	0.50	0.50	No.
57160	Fitting and insertion of pessary or other intravaginal support device.	0.89	0.89	0.89	No.
58100	Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure).	1.53	1.21	1.21	No.
58110	Endometrial sampling (biopsy) performed in conjunction with colposcopy.	0.77	0.77	0.77	No.
64405	Injection, anesthetic agent; greater occipital nerve	0.94	0.94	0.94	No.
64455	Injection(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (e.g., Morton's neuroma).	0.75	0.75	0.75	No.
65205	Removal of foreign body, external eye; conjunctival superficial.	0.71	0.49	0.49	No.
65210	Removal of foreign body, external eye; conjunctival embedded (includes concretions), subconjunctival, or scleral nonpenetrating.	0.84	0.75	0.61	No.
67500	Retrobulbar injection; medication (separate procedure, does not include supply of medication).	1.44	1.18	1.18	No.
67505	Retrobulbar injection; & alcohol	1.27	1.18	0.94	No.
67515	Injection of medication or other substance into Tenon's capsule.	1.40	0.84	0.75	No.
72020	Radiologic examination, spine, single view, specify level ..	0.15	0.15	0.23	No.
72040	Radiologic examination, spine, cervical; 2 or 3 views	0.22	0.22	0.23	No.
72050	Radiologic examination, spine, cervical; 4 or 5 views	0.31	0.31	0.23	No.
72052	Radiologic examination, spine, cervical; 6 or more views	0.36	0.35	0.23	No.
72070	Radiologic examination, spine; thoracic, 2 views	0.22	0.22	0.23	No.
72072	Radiologic examination, spine; thoracic, 3 views	0.22	0.22	0.23	No.
72074	Radiologic examination, spine; thoracic, minimum of 4 views.	0.22	0.22	0.23	No.
72080	Radiologic examination, spine; thoracolumbar junction, minimum of 2 views.	0.22	0.22	0.23	No.
72100	Radiologic examination, spine, lumbosacral; 2 or 3 views	0.22	0.22	0.23	No.
72110	Radiologic examination, spine, lumbosacral; minimum of 4 views.	0.31	0.31	0.23	No.
72114	Radiologic examination, spine, lumbosacral; complete, including bending views, minimum of 6 views.	0.32	0.31	0.23	No.

TABLE 13—CY 2019 PROPOSED WORK RVUS FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
72120	Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views.	0.22	0.22	0.23	No.
72200	Radiologic examination, sacroiliac joints; less than 3 views.	0.17	0.17	0.23	No.
72202	Radiologic examination, sacroiliac joints; 3 or more views	0.19	0.18	0.23	No.
72220	Radiologic examination, sacrum and coccyx, minimum of 2 views.	0.17	0.17	0.23	No.
73070	Radiologic examination, elbow; 2 views	0.15	0.15	0.23	No.
73080	Radiologic examination, elbow; complete, minimum of 3 views.	0.17	0.17	0.23	No.
73090	Radiologic examination; forearm, 2 views	0.16	0.16	0.23	No.
73650	Radiologic examination; calcaneus, minimum of 2 views ..	0.16	0.16	0.23	No.
73660	Radiologic examination; toe(s), minimum of 2 views	0.13	0.13	0.23	No.
74210	Radiologic examination; pharynx and/or cervical esophagus.	0.36	0.59	0.59	No.
74220	Radiologic examination; esophagus	0.46	0.67	0.67	No.
74230	Swallowing function, with cineradiography/ videoradiography.	0.53	0.53	0.53	No.
74420	Urography, retrograde, with or without KUB	0.36	0.52	0.52	No.
74485	Dilation of ureter(s) or urethra, radiological supervision and interpretation.	0.54	0.83	0.83	No.
76000	Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health care professional time, other than 71023 or 71034 (e.g., cardiac fluoroscopy).	0.17	0.30	0.30	No.
76514	Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness).	0.17	0.17	0.14	No.
767X1	Ultrasound, elastography; parenchyma (e.g., organ)	NEW	0.59	0.59	No.
767X2	Ultrasound, elastography; first target lesion	NEW	0.59	0.59	No.
767X3	Ultrasound, elastography; each additional target lesion ...	NEW	0.50	0.50	No.
76870	Ultrasound, scrotum and contents	0.64	0.64	0.64	No.
76942	Ultrasonic guidance for needle placement (e.g., biopsy, fine needle aspiration biopsy, injection, localization device), imaging supervision and interpretation.	0.67	0.67	0.67	No.
76X01	Magnetic resonance (e.g., vibration) elastography	NEW	1.29	1.10	No.
76X0X	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion.	NEW	1.62	1.27	No.
76X1X	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection.	NEW	0.85	0.85	No.
77012	Computed tomography guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), radiological supervision and interpretation.	1.16	1.50	1.50	No.
77021	Magnetic resonance guidance for needle placement (e.g., for biopsy, fine needle aspiration biopsy, injection, or placement of localization device) radiological supervision and interpretation.	1.50	1.50	1.50	No.
77081	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel).	0.22	0.20	0.20	No.
77X49	Magnetic resonance imaging, breast, without contrast material; unilateral.	NEW	1.45	1.15	No.
77X50	Magnetic resonance imaging, breast, without contrast material; bilateral.	NEW	1.60	1.30	No.
77X51	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD-real time lesion detection, characterization and pharmacokinetic analysis) when performed; unilateral.	NEW	2.10	1.80	No.
77X52	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD-real time lesion detection, characterization and pharmacokinetic analysis) when performed; bilateral.	NEW	2.30	2.00	No.
85060	Blood smear, peripheral, interpretation by physician with written report.	0.45	0.45	0.36	No.
85097	Bone marrow, smear interpretation	0.94	1.00	0.94	No.
85390	Fibrinolysins or coagulopathy screen, interpretation and report.	0.37	0.75	0.75	No.
92X71	Electroretinography (ERG) with interpretation and report; full field (e.g., ffERG, flash ERG, Ganzfeld ERG).	NEW	0.80	0.69	No.
92X73	Electroretinography (ERG) with interpretation and report; multifocal (mfERG).	NEW	0.72	0.61	No.

TABLE 13—CY 2019 PROPOSED WORK RVUS FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
93561	Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; with cardiac output measurement.	0.25	0.95	0.60	No.
93562	Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; subsequent measurement of cardiac output.	0.01	0.77	0.48	No.
93571	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel.	1.80	1.50	1.38	No.
93572	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel.	1.44	1.00	1.00	No.
93668	Peripheral arterial disease (PAD) rehabilitation, per session.	0.00	0.00	0.00	No.
93XX1	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional.	NEW	0.70	0.70	No.
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time.	1.05	1.00	0.85	No.
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and/respiratory analysis (e.g., by airflow or peripheral arterial tone).	1.00	1.00	0.85	No.
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement).	1.25	1.08	0.93	No.
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve neurostimulator pulse generator/transmitter, without programming.	0.45	0.45	0.35	No.
95X83	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional.	NEW	0.95	0.73	No.
95X84	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional.	NEW	1.19	0.97	No.

TABLE 13—CY 2019 PROPOSED WORK RVUS FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCCPS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
95X85	Electronic analysis of implanted neurostimulator pulse generator/transmitter (<i>e.g.</i> , contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional.	NEW	1.25	0.91	No.
95X86	Electronic analysis of implanted neurostimulator pulse generator/transmitter (<i>e.g.</i> , contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional.	NEW	1.00	0.80	No.
96105	Assessment of aphasia (includes assessment of expressive and receptive speech and language function, language comprehension, speech production ability, reading, spelling, writing, <i>e.g.</i> , by boston diagnostic aphasia examination) with interpretation and report, per hour.	1.75	1.75	1.75	No.
96110	Developmental screening (<i>e.g.</i> , developmental milestone survey, speech and language delay screen) with scoring and documentation, per standardized instrument.	0.00	0.00	0.00	No.
96116	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, <i>e.g.</i> , acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour.	1.86	1.86	1.86	No.
96125	Standardized cognitive performance testing (<i>e.g.</i> , ross information processing assessment) per hour of a qualified health care professional's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report.	1.70	1.70	1.70	No.
96127	Brief emotional/behavioral assessment (<i>e.g.</i> , depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument.	0.00	0.00	0.00	No.
963X0	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour.	NEW	2.50	2.56	No.
963X1	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes.	NEW	1.10	1.16	No.
963X2	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, <i>e.g.</i> , acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour.	NEW	1.71	1.71	No.

TABLE 13—CY 2019 PROPOSED WORK RVUS FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
963X3	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour.	NEW	2.50	2.56	No.
963X4	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour.	NEW	1.90	1.96	No.
963X5	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour.	NEW	2.50	2.56	No.
963X6	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour.	NEW	1.90	1.96	No.
963X7	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method, first 30 minutes.	NEW	0.55	0.55	No.
963X8	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method, each additional 30 minutes.	NEW	0.46	0.46	No.
963X9	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes.	NEW	0.00	0.00	No.
96X00	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and report, up to 30 days.	NEW	2.30	1.98	No.
96X10	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes.	NEW	0.00	0.00	No.
96X11	Psychological or neuropsychological test administration using single instrument, with interpretation and report by physician or other qualified health care professional and interactive feedback to the patient, family member(s), or caregivers(s), when performed.	NEW	0.51	0.51	No.
96X12	Psychological or neuropsychological test administration, with single automated instrument via electronic platform, with automated result only.	NEW	0.00	0.00	No.
990X0	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment.	NEW	0.00	0.00	No.
990X1	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days.	NEW	0.00	0.00	No.

TABLE 13—CY 2019 PROPOSED WORK RVUS FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
99201	Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family.	0.48	0.48	0.48	No.
99202	Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.	0.93	0.93	1.90	Yes.
99203	Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.	1.42	1.42	1.90	Yes.
99204	Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.	2.43	2.43	1.90	Yes.
99205	Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.	3.17	3.17	1.90	Yes.
99211	Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.	0.18	0.18	0.18	No.

TABLE 13—CY 2019 PROPOSED WORK RVUS FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straight-forward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family.	0.48	0.48	1.22	Yes.
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family.	0.97	0.97	1.22	Yes.
99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.	1.50	1.50	1.22	Yes.
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.	2.11	2.11	1.22	Yes.
99446	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified healthcare professional; 5–10 minutes of medical consultative discussion and review.	B	0.35	0.35	No.
99447	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified healthcare professional; 11–20 minutes of medical consultative discussion and review.	B	0.70	0.70	No.
99448	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified healthcare professional; 21–30 minutes of medical consultative discussion and review.	B	1.05	1.05	No.

TABLE 13—CY 2019 PROPOSED WORK RVUS FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCCPS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
99449	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified healthcare professional; 31 minutes or more of medical consultative discussion and review.	B	1.40	1.40	No.
994X0	Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes.	NEW	0.50	0.50	No.
994X6	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time.	NEW	0.70	0.50	No.
994X7	CCM provided personally by a physician/QHP	NEW	1.45	1.22	No.
994X9	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month.	NEW	0.61	0.61	No.
G0108	Diabetes outpatient self-management training services, individual, per 30 minutes.	0.90	0.90	0.90	No.
G0109	Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes.	0.25	0.25	0.25	No.
G0166	External counterpulsation, per treatment session	0.07	0.00	0.00	No.
G0168	Wound closure utilizing tissue adhesive(s) only	0.45	0.45	0.31	No.
G0268	Removal of impacted cerumen (one or both ears) by physician on same date of service as audiologic function testing.	0.61	0.61	0.61	No.
GCG0X	Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit).	NEW	0.25	No.
GPC1X	Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an evaluation and management visit).	NEW	0.07	No.
GPD0X	Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, new patient.	NEW	1.35	No.
GPD1X	Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, established patient.	NEW	0.85	No.
GPRO1	Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service).	NEW	1.17	No.
GRAS1	Remote pre-recorded service via recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment.	NEW	0.18	No.
GSBR1	Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., audit, dast), and brief intervention, 5–14 minutes.	NEW	0.33	No.

TABLE 13—CY 2019 PROPOSED WORK RVUS FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
GVC11	Brief communication technology-based service, <i>e.g.</i> , virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion.	NEW	0.25	No.

BILLING CODE 4120–01–P

TABLE 14: CY 2019 Proposed Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
10021	Fna bx w/o img gdn 1st les	EF015	mayo stand	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10021	Fna bx w/o img gdn 1st les	EF023	table, exam	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
10X12	Fna bx w/us gdn 1st les	EF015	mayo stand	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10X12	Fna bx w/us gdn 1st les	EF023	table, exam	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
10X12	Fna bx w/us gdn 1st les	EQ250	ultrasound unit, portable	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.26
10X14	Fna bx w/fluor gdn	ED050	Technologist	NF		49	47	E1: Refined	-0.04

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	1st les		PACS workstation					equipment time to conform to established policies for non-highly technical equipment	
10X14	Fna bx w/fluor gdn 1st les	EF015	mayo stand	NF		44	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10X14	Fna bx w/fluor gdn 1st les	EL014	room, radiographic-fluoroscopic	NF		44	34	E2: Refined equipment time to conform to established policies for highly technical equipment	-16.87
10X16	Fna bx w/ct gdn 1st les	EF015	mayo stand	NF		52	50	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
11755	Biopsy nail unit	EF015	mayo stand	NF		29	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
11755	Biopsy nail unit	EF031	table, power	NF		29	25	E1: Refined equipment time to conform to established policies for non-highly	-0.06

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								technical equipment	
11755	Biopsy nail unit	EQ137	instrument pack, basic (\$500-\$1499)	NF		39	31	E5: Refined equipment time to conform to established policies for surgical instrument packs	-0.02
11755	Biopsy nail unit	EQ168	light, exam	NF		29	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
11X02	Tangntl bx skin single les	EF015	mayo stand	NF		13	11	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
11X02	Tangntl bx skin single les	EF031	table, power	NF		13	11	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
11X02	Tangntl bx skin single les	EQ168	light, exam	NF		13	11	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
11X02	Tangntl bx skin single les	L037D	RN/LPN/MTA	NF	Review home care	2	0	G8: Input removed; code is typically	-0.74

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					instructions, coordinate visits/prescriptions			billed with an E/M or other evaluation service	
11X02	Tangntl bx skin single les	SB027	gown, staff, impervious	NF		2	1	S1: Duplicative; supply is included in SA043	-1.19
11X02	Tangntl bx skin single les	SB034	mask, surgical, with face shield	NF		2	1	S1: Duplicative; supply is included in SA043	-1.22
11X03	Tangntl bx skin ea sep/addl	SB011	drape, sterile, fenestrated 16in x 29in	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.58
11X03	Tangntl bx skin ea sep/addl	SB024	gloves, sterile	NF		2	0	S9: Add-on code. Additional supplies not typical; see preamble text	-1.72
11X03	Tangntl bx skin ea sep/addl	SC080	needle, OSHA compliant (SafetyGlide)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.54
11X03	Tangntl bx skin ea sep/addl	SF047	scalpel, safety, surgical, with blade (#10-20)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-2.85
11X03	Tangntl bx skin ea sep/addl	SG033	dressing, 12-7mm (Gelfoam)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-9.88
11X03	Tangntl bx skin ea sep/addl	SG035	dressing, 3in x 4in (Telfa, Release)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.12

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
11X03	Tangntl bx skin ea sep/addl	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.61
11X03	Tangntl bx skin ea sep/addl	SG079	tape, surgical paper 1in (Micropore)	NF		6	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.02
11X03	Tangntl bx skin ea sep/addl	SJ081	swab, patient prep, 1.5 ml (chloraprep)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-1.05
11X04	Punch bx skin single lesion	EF015	mayo stand	NF		19	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
11X04	Punch bx skin single lesion	EF031	table, power	NF		19	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
11X04	Punch bx skin single lesion	EQ114	electrosurgical generator, up to 120 watts	NF		19	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
11X04	Punch bx skin single lesion	EQ168	light, exam	NF		19	17	E1: Refined equipment time to conform to established policies	-0.01

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								for non-highly technical equipment	
11X04	Punch bx skin single lesion	EQ351	Smoke Evacuator(tubing, covering, etc.) with stand	NF		19	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
11X04	Punch bx skin single lesion	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescriptions	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
11X04	Punch bx skin single lesion	SB027	gown, staff, impervious	NF		2	1	S1: Duplicative; supply is included in SA043	-1.19
11X04	Punch bx skin single lesion	SB034	mask, surgical, with face shield	NF		2	1	S1: Duplicative; supply is included in SA043	-1.22
11X05	Punch bx skin ea sep/addl	SB011	drape, sterile, fenestrated 16in x 29in	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.58
11X05	Punch bx skin ea sep/addl	SB024	gloves, sterile	NF		2	0	S9: Add-on code. Additional supplies not typical; see preamble text	-1.72
11X05	Punch bx skin ea sep/addl	SC080	needle, OSHA compliant (SafetyGlide)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.54
11X05	Punch bx skin ea sep/addl	SF036	suture, nylon, 3-0 to 6-0, c	NF		1	0	S9: Add-on code. Additional supplies	-2.60

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								not typical; see preamble text	
11X05	Punch bx skin ea sep/addl	SF040	suture, vicryl, 3-0 to 6-0, p, ps	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-6.97
11X05	Punch bx skin ea sep/addl	SG035	dressing, 3in x 4in (Telfa, Release)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.12
11X05	Punch bx skin ea sep/addl	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.61
11X05	Punch bx skin ea sep/addl	SG079	tape, surgical paper 1in (Micropore)	NF		6	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.02
11X05	Punch bx skin ea sep/addl	SJ081	swab, patient prep, 1.5 ml (chloraprep)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-1.05
11X06	Incal bx skn single les	EF015	mayo stand	NF		33	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
11X06	Incal bx skn single les	EF031	table, power	NF		33	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
11X06	Incal bx skn single les	EQ114	electrosurgical generator, up to 120 watts	NF		33	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
11X06	Incal bx skn single les	EQ168	light, exam	NF		33	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
11X06	Incal bx skn single les	EQ351	Smoke Evacuator(tubing, covering, etc.) with stand	NF		33	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
11X06	Incal bx skn single les	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescriptions	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
11X06	Incal bx skn single les	SB027	gown, staff, impervious	NF		2	1	S1: Duplicative; supply is included in SA043	-1.19
11X06	Incal bx skn single les	SB034	mask, surgical, with face shield	NF		2	1	S1: Duplicative; supply is included in SA043	-1.22
11X07	Incal bx skn ea sep/addl	SB011	drape, sterile, fenestrated 16in x 29in	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.58

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
11X07	Incal bx skn ea sep/addl	SB024	gloves, sterile	NF		2	0	S9: Add-on code. Additional supplies not typical; see preamble text	-1.72
11X07	Incal bx skn ea sep/addl	SC080	needle, OSHA compliant (SafetyGlide)	NF		2	0	S9: Add-on code. Additional supplies not typical; see preamble text	-1.07
11X07	Incal bx skn ea sep/addl	SF036	suture, nylon, 3-0 to 6-0, c	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-2.60
11X07	Incal bx skn ea sep/addl	SF040	suture, vicryl, 3-0 to 6-0, p, ps	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-6.97
11X07	Incal bx skn ea sep/addl	SF047	scalpel, safety, surgical, with blade (#10-20)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-2.85
11X07	Incal bx skn ea sep/addl	SG035	dressing, 3in x 4in (Telfa, Release)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.12
11X07	Incal bx skn ea sep/addl	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF		1	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.61
11X07	Incal bx skn ea sep/addl	SG079	tape, surgical paper 1in (Micropore)	NF		12	0	S9: Add-on code. Additional supplies not typical; see preamble text	-0.05
11X07	Incal bx skn ea sep/addl	SJ081	swab, patient prep, 1.5 ml	NF		1	0	S9: Add-on code. Additional supplies	-1.05

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			(chloraprep)					not typical; see preamble text	
20551	Inj tendon origin/insertion	EF023	table, exam	NF		19	14	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
20551	Inj tendon origin/insertion	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescriptions	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
20551	Inj tendon origin/insertion	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-1.11
27X69	Njx cntrst kne arthg/ct/mri	EL014	room, radiographic-fluoroscopic	NF		22	23	E15: Refined equipment time to conform to changes in clinical labor time	1.69
27X69	Njx cntrst kne arthg/ct/mri	L041B	Radiologic Technologist	NF	Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue.	1	0	G1: See preamble text	-0.41
27X69	Njx cntrst kne arthg/ct/mri	L041B	Radiologic Technologist	NF	Confirm order,	1	0	G1: See preamble text	-0.41

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					protocol exam				
27X69	Njx cntrst kne arthg/ct/mri	L041B	Radiologic Technologist	NF	Prepare room, equipment and supplies	2	3	L1: Refined time to standard for this clinical labor task	0.41
29105	Apply long arm splint	EF031	table, power	NF		51	49	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
29105	Apply long arm splint	EQ080	cast cart	NF		51	49	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
29105	Apply long arm splint	EQ081	cast cutter	NF		51	49	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
29105	Apply long arm splint	EQ082	cast vacuum	NF		51	49	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
29540	Strapping of ankle and/or ft	EF031	table, power	NF		20	17	E1: Refined equipment time to conform to established policies	-0.05

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								for non-highly technical equipment	
29540	Strapping of ankle and/or ft	EQ168	light, exam	NF		20	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
29540	Strapping of ankle and/or ft	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescriptions	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
29540	Strapping of ankle and/or ft	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
29550	Strapping of toes	EF031	table, power	NF		16	13	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.05
29550	Strapping of toes	EQ168	light, exam	NF		16	13	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
29550	Strapping of toes	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescri	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					ptions				
29550	Strapping of toes	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
31623	Dx bronchoscope/brush	EF031	table, power	NF		44	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.11
31623	Dx bronchoscope/brush	EQ004	CO2 respiratory profile monitor	NF		34	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.39
31623	Dx bronchoscope/brush	EQ235	suction machine (Gomco)	NF		34	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
31623	Dx bronchoscope/brush	ES017	fiberscope, flexible, bronchoscopy	NF		74	69	E4: Refined equipment time to conform to established policies for scopes	-0.43
31623	Dx bronchoscope/brush	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		44	42	E19: Refined equipment time to conform to established policies for scope accessories	-0.28
31623	Dx	L047C	RN/Respiratory	NF	Complete	4	2	L1: Refined time to	-0.94

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	bronchoscope/brush		Therapist		post-procedure diagnostic forms, lab and x-ray requisitions			standard for this clinical labor task	
31624	Dx bronchoscope/lavage	EF031	table, power	NF		44	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.11
31624	Dx bronchoscope/lavage	EQ004	CO2 respiratory profile monitor	NF		34	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.39
31624	Dx bronchoscope/lavage	EQ235	suction machine (Gomco)	NF		34	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
31624	Dx bronchoscope/lavage	ES017	fiberscope, flexible, bronchoscopy	NF		74	69	E4: Refined equipment time to conform to established policies for scopes	-0.43
31624	Dx bronchoscope/lavage	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		44	42	E19: Refined equipment time to conform to established policies for scope accessories	-0.28

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31624	Dx bronchoscope/lavage	L047C	RN/Respiratory Therapist	NF	Complete post-procedure diagnostic forms, lab and x-ray requisitions	4	2	L1: Refined time to standard for this clinical labor task	-0.94
335X1	Rplcmt a-valve tlcj autol pv	L051A	RN	F	Provide pre-service education/obtain consent	26	20	L1: Refined time to standard for this clinical labor task	-3.06
335X1	Rplcmt a-valve tlcj autol pv	L051A	RN	F	Perform regulatory mandated quality assurance activity (pre-service)	0	15	G1: See preamble text	7.65
335X1	Rplcmt a-valve tlcj autol pv	L051A	RN	F	Coordinate pre-surgery services (including test results)	25	20	L1: Refined time to standard for this clinical labor task	-2.55
335X1	Rplcmt a-valve tlcj autol pv	L051A	RN	F	Schedule space and equipment in facility	12	8	L1: Refined time to standard for this clinical labor task	-2.04
36X72	Insj picc rs&i <5 yr	ED050	Technologist PACS workstation	NF		54	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
36X72	Insj picc rs&i <5 yr	EL014	room, radiographic-fluoroscopic	NF		33	31	E15: Refined equipment time to conform to changes	-3.37

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								in clinical labor time	
36X72	Insj picc rs&i <5 yr	EQ250	ultrasound unit, portable	NF		49	47	E15: Refined equipment time to conform to changes in clinical labor time	-0.26
36X72	Insj picc rs&i <5 yr	L041B	Radiologic Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	4	2	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-0.82
36X73	Insj picc rs&i 5 yr+	ED050	Technologist PACS workstation	NF		49	47	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
36X73	Insj picc rs&i 5 yr+	EL014	room, radiographic-fluoroscopic	NF		26	24	E15: Refined equipment time to conform to changes in clinical labor time	-3.37
36X73	Insj picc rs&i 5 yr+	EQ250	ultrasound unit, portable	NF		44	42	E15: Refined equipment time to conform to changes in clinical labor time	-0.26
36X73	Insj picc rs&i 5 yr+	L041B	Radiologic Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	4	2	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-0.82
38792	Ra tracer id of sentinel node	ED020	computer workstation,	NF		18	19	E15: Refined equipment time to	0.05

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			nuclear pharmacy management (hardware and software)					conform to changes in clinical labor time	
38792	Ra tracer id of sentinel node	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.00
38792	Ra tracer id of sentinel node	ER027	dose calibrator (Atomlab)	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.03
38792	Ra tracer id of sentinel node	ER033	gamma counter, automatic	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.07
38792	Ra tracer id of sentinel node	ER053	radiation L-block tabletop shield	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.00
38792	Ra tracer id of sentinel node	ER054	radiation survey meter	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.00
38792	Ra tracer id of sentinel node	ER058	safe, storage, lead-lined	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.01
38792	Ra tracer id of sentinel node	L049A	Nuclear Medicine Technologist	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.62
38792	Ra tracer id of sentinel node	L049A	Nuclear Medicine Technologist	NF	Prepare room,	2	3	L1: Refined time to standard for this	0.62

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					equipment and supplies			clinical labor task	
43X63	Rplc gtube no revj trc	EF023	table, exam	NF		22	23	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
43X64	Rplc gtube revj gstrst trc	EF014	light, surgical	NF		34	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.01
43X64	Rplc gtube revj gstrst trc	EF015	mayo stand	NF		34	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
43X64	Rplc gtube revj gstrst trc	EF031	table, power	NF		34	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.02
45300	Proctosigmoidoscopy dx	EF031	table, power	NF		30	28	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
45300	Proctosigmoidoscopy dx	EQ235	suction machine (Gomco)	NF		30	28	E1: Refined equipment time to	0.00

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								conform to established policies for non-highly technical equipment	
45300	Proctosigmoidoscopy dx	ES003	cart, endoscopy imaging equipment	NF		30	28	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
45300	Proctosigmoidoscopy dx	ES012	endoscope, rigid, sigmoidoscopy	NF		40	34	E4: Refined equipment time to conform to established policies for scopes	-0.03
46500	Injection into hemorrhoid(s)	ES002	anoscope with light source	NF		75	72	E4: Refined equipment time to conform to established policies for scopes	-0.09
46500	Injection into hemorrhoid(s)	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional ---directly related to physician work time (100% of physician intra-service time)	10	0	G1: See preamble text	-3.70

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46500	Injection into hemorrhoid(s)	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescriptions	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
46500	Injection into hemorrhoid(s)	SB027	gown, staff, impervious	NF		3	2	S6: Refined supply quantity to what is typical for the procedure	-1.19
46500	Injection into hemorrhoid(s)	SB034	mask, surgical, with face shield	NF		3	2	S6: Refined supply quantity to what is typical for the procedure	-1.22
46500	Injection into hemorrhoid(s)	SB039	shoe covers, surgical	NF		3	2	S6: Refined supply quantity to what is typical for the procedure	-0.28
52334	Create passage to kidney	L041B	Radiologic Technologist	F	Confirm availability of prior images/studies	2	0	G1: See preamble text	-0.82
58100	Biopsy of uterus lining	EF031	table, power	NF		26	22	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.06
58100	Biopsy of uterus lining	EQ168	light, exam	NF		26	22	E1: Refined equipment time to conform to established policies for non-highly	-0.02

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								technical equipment	
58100	Biopsy of uterus lining	L037D	RN/LPN/MTA	NF	Review/read post-procedure x-ray, lab and pathology reports	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
64405	N block inj occipital	EF023	table, exam	NF		18	16	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
64455	N block inj plantar digit	EF023	table, exam	NF		19	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
72020	X-ray exam of spine 1 view	EL012	room, basic radiology	NF		10	8	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72040	X-ray exam neck spine 2-3 vw	EL012	room, basic radiology	NF		18	16	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72050	X-ray exam neck spine 4/5vws	EL012	room, basic radiology	NF		24	22	E2: Refined equipment time to	-1.19

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								conform to established policies for highly technical equipment	
72052	X-ray exam neck spine 6/>vws	EL012	room, basic radiology	NF		30	28	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72070	X-ray exam thorac spine 2vws	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72072	X-ray exam thorac spine 3vws	EL012	room, basic radiology	NF		18	16	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72074	X-ray exam thorac spine4/>vw	EL012	room, basic radiology	NF		21	19	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72080	X-ray exam thoracolmb 2/> vw	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
72100	X-ray exam l-s spine 2/3 vws	EL012	room, basic radiology	NF		18	16	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72110	X-ray exam l-2 spine 4/>vws	EL012	room, basic radiology	NF		24	22	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72114	X-ray exam l-s spine bending	EL012	room, basic radiology	NF		30	28	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72120	X-ray bend only l-s spine	EL012	room, basic radiology	NF		20	18	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72120	X-ray bend only l-s spine	SB026	gown, patient	NF		0	1	S5: Refined supply quantity to conform with other codes in the family	1.28
72200	X-ray exam si joints	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
72202	X-ray exam si joints 3/> vws	EL012	room, basic radiology	NF		18	16	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72220	X-ray exam sacrum tailbone	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
73070	X-ray exam of elbow	EL012	room, basic radiology	NF		13	11	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
73080	X-ray exam of elbow	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
73090	X-ray exam of forearm	EL012	room, basic radiology	NF		13	11	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
73650	X-ray exam of heel	EL012	room, basic radiology	NF		13	11	E2: Refined equipment time to conform to established policies	-1.19

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								for highly technical equipment	
73660	X-ray exam of toe(s)	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
73660	X-ray exam of toe(s)	SB026	gown, patient	NF		0	1	S5: Refined supply quantity to conform with other codes in the family	1.28
74210	Contrst x-ray exam of throat	EL014	room, radiographic-fluoroscopic	NF		22	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-3.37
74220	Contrast x-ray esophagus	EL014	room, radiographic-fluoroscopic	NF		22	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-3.37
74230	Cine/vid x-ray throat/esoph	EF008	chair with headrest, exam, reclining	NF		28	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
74230	Cine/vid x-ray throat/esoph	EL014	room, radiographic-fluoroscopic	NF		28	26	E2: Refined equipment time to conform to established policies	-3.37

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								for highly technical equipment	
74420	Contrst x-ray urinary tract	ED050	Technologist PACS workstation	NF		39	38	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
74420	Contrst x-ray urinary tract	ED053	Professional PACS Workstation	NF		20	18	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.12
74420	Contrst x-ray urinary tract	EL012	room, basic radiology	NF		35	33	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
74420	Contrst x-ray urinary tract	L041B	Radiologic Technologist	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.41
76000	Fluoroscopy <1 hr phys/qlhp	ER031	fluoroscopic system, mobile C-Arm	NF		19	17	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.51
767X1	Use parenchyma	ED060	sheer wave elastography software	NF		28	29	E15: Refined equipment time to conform to changes in clinical labor time	0.04
767X1	Use parenchyma	EL015	room, ultrasound, general	NF		28	29	E15: Refined equipment time to	1.17

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								conform to changes in clinical labor time	
767X1	Use parenchyma	L050B	Diagnostic Medical Sonographer	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.50
767X1	Use parenchyma	L050B	Diagnostic Medical Sonographer	NF	Prepare room, equipment and supplies	2	3	L1: Refined time to standard for this clinical labor task	0.50
767X2	Use 1st target lesion	ED060	sheer wave elastography software	NF		23	24	E15: Refined equipment time to conform to changes in clinical labor time	0.04
767X2	Use 1st target lesion	EL015	room, ultrasound, general	NF		23	24	E15: Refined equipment time to conform to changes in clinical labor time	1.17
767X2	Use 1st target lesion	L050B	Diagnostic Medical Sonographer	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.50
767X2	Use 1st target lesion	L050B	Diagnostic Medical Sonographer	NF	Prepare room, equipment and supplies	2	3	L1: Refined time to standard for this clinical labor task	0.50
76870	Us exam scrotum	ED050	Technologist PACS workstation	NF		39	36	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.07
76870	Us exam scrotum	EL015	room, ultrasound, general	NF		29	28	E2: Refined equipment time to	-1.17

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								conform to established policies for highly technical equipment	
76870	Us exam scrotum	L051B	RN/Diagnostic Medical Sonographer	NF	Prepare room, equipment and supplies	2	3	L1: Refined time to standard for this clinical labor task	0.51
76870	Us exam scrotum	L051B	RN/Diagnostic Medical Sonographer	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.51
76X01	Mr elastography	ED050	Technologist PACS workstation	NF		52	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
76X01	Mr elastography	EL008	room, MR	NF		38	36	E15: Refined equipment time to conform to changes in clinical labor time	-6.71
76X01	Mr elastography	EL050	MR Elastography Package	NF		38	36	E15: Refined equipment time to conform to changes in clinical labor time	-0.84
76X01	Mr elastography	L047A	MRI Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	4	3	L1: Refined time to standard for this clinical labor task	-0.47
76X01	Mr elastography	L047A	MRI Technologist	NF	Prepare room, equipment	6	5	L1: Refined time to standard for this clinical labor task	-0.47

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					and supplies				
76X0X	Us trgt dyn mbubb 1st les	EL015	room, ultrasound, general	NF		37	38	E15: Refined equipment time to conform to changes in clinical labor time	1.17
76X0X	Us trgt dyn mbubb 1st les	ER108	Ultrasound Contrast Imaging Package	NF		37	38	E15: Refined equipment time to conform to changes in clinical labor time	0.02
76X0X	Us trgt dyn mbubb 1st les	L050B	Diagnostic Medical Sonographer	NF	Prepare room, equipment and supplies	2	3	L1: Refined time to standard for this clinical labor task	0.50
76X0X	Us trgt dyn mbubb 1st les	L050B	Diagnostic Medical Sonographer	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.50
76X0X	Us trgt dyn mbubb 1st les	SL180	phosphate buffered saline (PBS)	NF		50	0	G1: See preamble text	-1.07
76X1X	Us trgt dyn mbubb ea addl	SL180	phosphate buffered saline (PBS)	NF		50	0	G1: See preamble text	-1.07
77012	Ct scan for needle biopsy	ED050	Technologist PACS workstation	NF		32	33	E18: Refined equipment time to conform to established policies for PACS Workstations	0.02
77012	Ct scan for needle biopsy	EL007	room, CT	NF		28	9	G1: See preamble text	-95.06
77012	Ct scan for needle biopsy	L041B	Radiologic Technologist	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.41

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
77012	Ct scan for needle biopsy	L041B	Radiologic Technologist	NF	Prepare room, equipment and supplies	2	3	L1: Refined time to standard for this clinical labor task	0.41
77021	Mri guidance ndl plmt rs&i	ED050	Technologist PACS workstation	NF		62	65	E18: Refined equipment time to conform to established policies for PACS Workstations	0.07
77021	Mri guidance ndl plmt rs&i	L047A	MRI Technologist	NF	Prepare room, equipment and supplies	2	3	L1: Refined time to standard for this clinical labor task	0.47
77021	Mri guidance ndl plmt rs&i	L047A	MRI Technologist	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.47
77X49	Mri breast c-unilateral	ED050	Technologist PACS workstation	NF		55	51	E15: Refined equipment time to conform to changes in clinical labor time	-0.09
77X49	Mri breast c-unilateral	EL008	room, MR	NF		43	36	E2: Refined equipment time to conform to established policies for highly technical equipment	-23.48
77X49	Mri breast c-unilateral	EQ388	Breast coil	NF		43	36	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.23

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77X49	Mri breast c-unilateral	L047A	MRI Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	7	3	G1: See preamble text	-1.88
77X50	Mri breast c-bilateral	ED050	Technologist PACS workstation	NF		55	51	E15: Refined equipment time to conform to changes in clinical labor time	-0.09
77X50	Mri breast c-bilateral	EL008	room, MR	NF		43	36	E2: Refined equipment time to conform to established policies for highly technical equipment	-23.48
77X50	Mri breast c-bilateral	EQ388	Breast coil	NF		43	36	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.23
77X50	Mri breast c-bilateral	L047A	MRI Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	7	3	G1: See preamble text	-1.88
77X51	Mri breast c-+ w/cad uni	ED050	Technologist PACS workstation	NF		79	75	E15: Refined equipment time to conform to changes in clinical labor time	-0.09

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
77X51	Mri breast c-+ w/cad uni	ED056	CAD Workstation (CPU + Color Monitor)	NF		79	75	E15: Refined equipment time to conform to changes in clinical labor time	-0.24
77X51	Mri breast c-+ w/cad uni	ED058	CAD Software	NF		79	75	E15: Refined equipment time to conform to changes in clinical labor time	-0.27
77X51	Mri breast c-+ w/cad uni	EL008	room, MR	NF		62	55	E2: Refined equipment time to conform to established policies for highly technical equipment	-23.48
77X51	Mri breast c-+ w/cad uni	EQ388	Breast coil	NF		62	55	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.23
77X51	Mri breast c-+ w/cad uni	L047A	MRI Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	9	5	G1: See preamble text	-1.88
77X52	Mri breast c-+ w/cad bi	ED050	Technologist PACS workstation	NF		79	75	E15: Refined equipment time to conform to changes in clinical labor time	-0.09
77X52	Mri breast c-+ w/cad bi	ED056	CAD Workstation (CPU + Color Monitor)	NF		79	75	E15: Refined equipment time to conform to changes	-0.24

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								in clinical labor time	
77X52	Mri breast c-+ w/cad bi	ED058	CAD Software	NF		79	75	E15: Refined equipment time to conform to changes in clinical labor time	-0.27
77X52	Mri breast c-+ w/cad bi	EL008	room, MR	NF		62	55	E2: Refined equipment time to conform to established policies for highly technical equipment	-23.48
77X52	Mri breast c-+ w/cad bi	EQ388	Breast coil	NF		62	55	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.23
77X52	Mri breast c-+ w/cad bi	L047A	MRI Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	9	5	G1: See preamble text	-1.88
85097	Bone marrow interpretation	L030A	Lab Tech/MTA	NF	Accession and enter information	4	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-1.20
85097	Bone marrow interpretation	L030A	Lab Tech/MTA	NF	File specimen, supplies,	1	0	G6: Indirect Practice Expense input and/or not individually	-0.30

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					and other materials			allocable to a particular patient for a particular service	
92X71	Full field erg w/i&r	EQ390	mfERG and ffERG electrodiagnostic unit	NF		74	71	E15: Refined equipment time to conform to changes in clinical labor time	-0.94
92X71	Full field erg w/i&r	EQ391	Contact lens electrode for mfERG and ffERG	NF		79	71	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
92X71	Full field erg w/i&r	EQ391	Contact lens electrode for mfERG and ffERG	NF		79	71	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
92X71	Full field erg w/i&r	L038A	COMT/COT/RN/CST	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.38
92X71	Full field erg w/i&r	L038A	COMT/COT/RN/CST	NF	Review examination with interpreting MD/DO	5	2	L1: Refined time to standard for this clinical labor task	-1.14
92X71	Full field erg w/i&r	L038A	COMT/COT/RN/CST	NF	Clean room/equipment by clinical staff	12	8	G1: See preamble text	-1.52
92X71	Full field erg w/i&r	L038A	COMT/COT/RN/CST	NF	Provide education/obtain consent	1	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.38

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
92X71	Full field erg w/i&r	L038A	COMT/COT/RN/CST	NF	Prepare room, equipment and supplies	2	3	L1: Refined time to standard for this clinical labor task	0.38
92X71	Full field erg w/i&r	L038A	COMT/COT/RN/CST	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-1.14
92X71	Full field erg w/i&r	L038A	COMT/COT/RN/CST	F	Complete pre-service diagnostic and referral forms	3	0	G4: This input is not applicable in the facility setting	-1.14
92X71	Full field erg w/i&r	L038A	COMT/COT/RN/CST	F	Complete pre-procedure phone calls and prescription	1	0	G4: This input is not applicable in the facility setting	-0.38
92X71	Full field erg w/i&r	L038A	COMT/COT/RN/CST	F	Schedule space and equipment in facility	3	0	G4: This input is not applicable in the facility setting	-1.14
92X71	Full field erg w/i&r	L038A	COMT/COT/RN/CST	F	Coordinate pre-surgery services (including test results)	3	0	G4: This input is not applicable in the facility setting	-1.14

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
92X71	Full field erg w/i&r	L038A	COMT/COT/RN/CST	NF	Technologist QC's images in PACS, checking for all images, reformats, and dose page	10	3	L1: Refined time to standard for this clinical labor task	-2.66
92X73	Multifocal erg w/i&r	EQ390	mfERG and fERG electrodiagnostic unit	NF		50	47	E15: Refined equipment time to conform to changes in clinical labor time	-0.94
92X73	Multifocal erg w/i&r	EQ391	Contact lens electrode for mfERG and fERG	NF		55	47	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
92X73	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-1.14
92X73	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Technologist QC's images in PACS, checking for all images, reformats, and dose	10	3	L1: Refined time to standard for this clinical labor task	-2.66

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					page				
92X73	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Clean room/equipment by clinical staff	12	8	G1: See preamble text	-1.52
92X73	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.38
92X73	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Provide education/obtain consent	1	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.38
92X73	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Review examination with interpreting MD/DO	5	2	L1: Refined time to standard for this clinical labor task	-1.14
92X73	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	F	Complete pre-service diagnostic and referral forms	3	0	G4: This input is not applicable in the facility setting	-1.14
92X73	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	F	Coordinate pre-surgery services (including test results)	3	0	G4: This input is not applicable in the facility setting	-1.14
92X73	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	F	Schedule space and equipment in facility	3	0	G4: This input is not applicable in the facility setting	-1.14

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
92X73	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	F	Complete pre-procedure phone calls and prescription	1	0	G4: This input is not applicable in the facility setting	-0.38
92X73	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Prepare room, equipment and supplies	2	3	L1: Refined time to standard for this clinical labor task	0.38
963X5	Nrpsyc tst eval phys/qhp 1st	SK130	WAIS-IV Record Form	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	5.25
963X5	Nrpsyc tst eval phys/qhp 1st	SK131	WAIS-IV Response Booklet #1	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	3.30
963X5	Nrpsyc tst eval phys/qhp 1st	SK132	WMS-IV Response Booklet #2	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	2.00
963X6	Nrpsyc tst eval phys/qhp ea	SK130	WAIS-IV Record Form	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	5.25
963X6	Nrpsyc tst eval phys/qhp ea	SK131	WAIS-IV Response Booklet #1	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	3.30
963X6	Nrpsyc tst eval phys/qhp ea	SK132	WMS-IV Response Booklet #2	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	2.00

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
963X7	Psycl/nrpsyc tst phy/qhp 1st	SK130	WAIS-IV Record Form	NF		0.2	1	S6: Refined supply quantity to what is typical for the procedure	4.38
963X7	Psycl/nrpsyc tst phy/qhp 1st	SK131	WAIS-IV Response Booklet #1	NF		0.2	1	S6: Refined supply quantity to what is typical for the procedure	2.76
963X7	Psycl/nrpsyc tst phy/qhp 1st	SK132	WMS-IV Response Booklet #2	NF		0.2	1	S6: Refined supply quantity to what is typical for the procedure	1.67
963X8	Psycl/nrpsyc tst phy/qhp ea	SK130	WAIS-IV Record Form	NF		0.2	1	S6: Refined supply quantity to what is typical for the procedure	4.38
963X8	Psycl/nrpsyc tst phy/qhp ea	SK131	WAIS-IV Response Booklet #1	NF		0.2	1	S6: Refined supply quantity to what is typical for the procedure	2.76
963X8	Psycl/nrpsyc tst phy/qhp ea	SK132	WMS-IV Response Booklet #2	NF		0.2	1	S6: Refined supply quantity to what is typical for the procedure	1.67
963X9	Psycl/nrpsyc tech 1st	SK130	WAIS-IV Record Form	NF		0.2	1	S6: Refined supply quantity to what is typical for the procedure	4.38
963X9	Psycl/nrpsyc tech 1st	SK131	WAIS-IV Response Booklet #1	NF		0.2	1	S6: Refined supply quantity to what is typical for the procedure	2.76
963X9	Psycl/nrpsyc tech 1st	SK132	WMS-IV Response Booklet	NF		0.2	1	S6: Refined supply quantity to what is	1.67

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			#2					typical for the procedure	
96X10	Psych/nrpsyc tst tech ea	SK130	WAIS-IV Record Form	NF		0.2	1	S6: Refined supply quantity to what is typical for the procedure	4.38
96X10	Psych/nrpsyc tst tech ea	SK131	WAIS-IV Response Booklet #1	NF		0.2	1	S6: Refined supply quantity to what is typical for the procedure	2.76
96X10	Psych/nrpsyc tst tech ea	SK132	WMS-IV Response Booklet #2	NF		0.2	1	S6: Refined supply quantity to what is typical for the procedure	1.67
96X12	Psych/nrpsyc tst auto result	ED055	CANTAB Mobile (per single automated assessment)	NF		10	0	G1: See preamble text	-0.11
990X1	Rem mntr physiol param dev		Monthly cellular and licensing service fee	NF		1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-69.00
99202	Office/outpatient visit new	EF023	table, exam	NF		39	51.4	G1: See preamble text	0.06
99202	Office/outpatient visit new	EQ189	otoscope-ophthalmoscope (wall unit)	NF		39	51.4	G1: See preamble text	0.02
99202	Office/outpatient visit new	L037D	RN/LPN/MTA	NF	Service total costs	39	55.3	G1: See preamble text	6.03
99203	Office/outpatient visit new	EF023	table, exam	NF		51	51.4	G1: See preamble text	0.00

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
99203	Office/outpatient visit new	EQ189	otoscope-ophthalmoscope (wall unit)	NF		51	51.4	G1: See preamble text	0.00
99203	Office/outpatient visit new	L037D	RN/LPN/MTA	NF	Service total costs	51	55.3	G1: See preamble text	1.59
99204	Office/outpatient visit new	EF023	table, exam	NF		51	51.4	G1: See preamble text	0.00
99204	Office/outpatient visit new	EQ189	otoscope-ophthalmoscope (wall unit)	NF		51	51.4	G1: See preamble text	0.00
99204	Office/outpatient visit new	L037D	RN/LPN/MTA	NF	Service total costs	51	51.4	G1: See preamble text	0.16
99204	Office/outpatient visit new	L037D	RN/LPN/MTA	NF	Preservice total costs	3	1.05	G1: See preamble text	-0.72
99204	Office/outpatient visit new	L037D	RN/LPN/MTA	NF	Post service total costs	8	2.81	G1: See preamble text	-1.92
99205	Office/outpatient visit new	EF023	table, exam	NF		71	51.4	G1: See preamble text	-0.10
99205	Office/outpatient visit new	EQ189	otoscope-ophthalmoscope (wall unit)	NF		71	51.4	G1: See preamble text	-0.04
99205	Office/outpatient visit new	L037D	RN/LPN/MTA	NF	Service total costs	71	55.3	G1: See preamble text	-5.81
99212	Office/outpatient visit est	EF023	table, exam	NF		28	39.5	G1: See preamble text	0.06
99212	Office/outpatient visit est	EQ189	otoscope-ophthalmoscope (wall unit)	NF		28	39.5	G1: See preamble text	0.02
99212	Office/outpatient visit est	L037D	RN/LPN/MTA	NF	Service total costs	28	44	G1: See preamble text	5.90
99213	Office/outpatient visit est	EF023	table, exam	NF		36	39.5	G1: See preamble text	0.02
99213	Office/outpatient	EQ189	otoscope-	NF		36	39.5	G1: See preamble	0.01

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	visit est		ophthalmoscope (wall unit)					text	
99213	Office/outpatient visit est	L037D	RN/LPN/MTA	NF	Service total costs	36	44	G1: See preamble text	2.94
99214	Office/outpatient visit est	EF023	table, exam	NF		44	39.5	G1: See preamble text	-0.02
99214	Office/outpatient visit est	EQ189	otoscope-ophthalmoscope (wall unit)	NF		44	39.5	G1: See preamble text	-0.01
99214	Office/outpatient visit est	L037D	RN/LPN/MTA	NF	Service total costs	44	39.5	G1: See preamble text	-1.65
99214	Office/outpatient visit est	L037D	RN/LPN/MTA	NF	Preservice total costs	3	1.47	G1: See preamble text	-0.57
99214	Office/outpatient visit est	L037D	RN/LPN/MTA	NF	Post service total costs	6	2.94	G1: See preamble text	-1.13
99215	Office/outpatient visit est	EF023	table, exam	NF		51	39.5	G1: See preamble text	-0.06
99215	Office/outpatient visit est	EQ189	otoscope-ophthalmoscope (wall unit)	NF		51	39.5	G1: See preamble text	-0.02
99215	Office/outpatient visit est	L037D	RN/LPN/MTA	NF	Service total costs	51	39.5	G1: See preamble text	-4.24
99215	Office/outpatient visit est	L037D	RN/LPN/MTA	NF	Preservice total costs	4	1.47	G1: See preamble text	-0.94
99215	Office/outpatient visit est	L037D	RN/LPN/MTA	NF	Post service total costs	8	2.94	G1: See preamble text	-1.87
G0108	Diab manage trn per indiv	ED021	computer, desktop, w-monitor	NF		0	10	G1: See preamble text	0.09
G0108	Diab manage trn per indiv	EF009	chair, medical recliner	NF		0	15	G1: See preamble text	0.05
G0108	Diab manage trn per indiv	EF016	scale, high capacity (800 lb)	NF		0	1	G1: See preamble text	0.00
G0108	Diab manage trn	EF025	table, for seated	NF		0	15	G1: See preamble	0.27

HCPSC code	HCPSC code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	per indiv		OT therapy					text	
G0108	Diab manage trn per indiv	EQ073	body analysis machine, bioimpedence	NF		0	2.5	G1: See preamble text	0.02
G0108	Diab manage trn per indiv	EQ123	food models	NF		0	10	G1: See preamble text	0.03
G0108	Diab manage trn per indiv	EQ187	nutrition therapy software (Nutritionist Pro)	NF		0	10	G1: See preamble text	0.02
G0108	Diab manage trn per indiv	L051A	RN	NF	Obtain vital signs	0	2	G1: See preamble text	1.02
G0108	Diab manage trn per indiv	SB022	gloves, non-sterile	NF		1	0	G1: See preamble text	-0.14
G0108	Diab manage trn per indiv	SK043	label for files-folders	NF		0	0.5	G1: See preamble text	0.04
G0108	Diab manage trn per indiv	SK057	paper, laser printing (cach sheet)	NF		2	4	G1: See preamble text	0.02
G0108	Diab manage trn per indiv	SK062	patient education booklet	NF		0	0.5	G1: See preamble text	0.93
G0108	Diab manage trn per indiv	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		1	0	G1: See preamble text	-0.05
G0109	Diab manage trn ind/group	ED021	computer, desktop, w-monitor	NF		0	3	G1: See preamble text	0.03
G0109	Diab manage trn ind/group	ED038	notebook (Dell Latitude D600)	NF		30	0	G1: See preamble text	-0.26
G0109	Diab manage trn ind/group	EF016	scale, high capacity (800 lb)	NF		0	1	G1: See preamble text	0.00
G0109	Diab manage trn ind/group	EF025	table, for seated OT therapy	NF		0	10	G1: See preamble text	0.18
G0109	Diab manage trn	EF043	Set of 8 chairs	NF		30	0	G1: See preamble	-0.31

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	ind/group							text	
G0109	Diab manage trn ind/group	EQ123	food models	NF		0	1	G1: See preamble text	0.00
G0109	Diab manage trn ind/group	EQ187	nutrition therapy software (Nutritionist Pro)	NF		0	1	G1: See preamble text	0.00
G0109	Diab manage trn ind/group	EQ282	PC projector	NF		30	0	G1: See preamble text	-0.32
G0109	Diab manage trn ind/group	EQ305	Diabetes education data tracking software	NF		2	4	G1: See preamble text	0.00
G0109	Diab manage trn ind/group	SK043	label for files-folders	NF		0	0.25	G1: See preamble text	0.02
G0109	Diab manage trn ind/group	SK062	patient education booklet	NF		0	0.1	G1: See preamble text	0.19
G0168	Wound closure by adhesive	EF023	table, exam	NF		10	9	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
G0268	Removal of impacted wax md	L037D	RN/LPN/MTA	NF	Clean surgical instrument package	3	0	G1: See preamble text	-1.11

TABLE 15—PROPOSED CY 2019 EXISTING INVOICES

CPT/HCPCS codes	Item name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
19085, 19086, 19287, 19288.	Breast MRI computer aided detection and biopsy guidance software.	EQ370	0.00	0.00		1	2,466
53850	kit, transurethral microwave thermotherapy.	SA036	1,149.00	1,000.00	– 13	1	5,608
53852	kit, transurethral needle ablation (TUNA).	SA037	1,050.00	900.00	– 14	2	2,476
85097	stain, Wright's Pack (per slide)	SL140	0.05	0.16	235	1	43,183
96116, 96118, 96119, 96125.	neurobehavioral status forms, average	SK050	5.77	4.00	– 31	3	414,139
258 codes	scope video system (monitor, processor, digital capture, cart, printer, LED light).	ES031	33,391.00	36,306.00	9		2,480,515

TABLE 16—PROPOSED CY 2019 NEW INVOICES

CPT/HCPCS codes	Item name	CMS code	Average price	Number of invoices	NF allowed services
10X18, 10X19	MREYE CHIBA BIOPSY NEEDLE	SC106	37.00	1	0
332X5	subcutaneous cardiac rhythm monitor system.	SA127	5,032.50	4	280
36X72, 36X73, 36584	Turbo-Ject PICC Line	SD331	170.00	1	24,402
538X3	kit, Rezum delivery device	SA128	1,150.00	1	121
538X3	generator, water thermotherapy procedure	EQ389	27,538.00	10	121
58100	Uterine Sound	SD329	3.17	1	59,152
58100	Tenaculum	SD330	3.77	1	59,152
767X1, 767X2, 767X3	sheer wave elastography software	ED060	9,600.00	1	493
76X01	MR Elastography Package	EL050	200,684.50	1	350
76X0X, 76X1X	bubble contrast	SD332	126.59	1	89
76X0X, 76X1X	Ultrasound Contrast Imaging Package	ER108	5,760.00	1	89
77X51, 77X52	CAD Software	ED058	17,200.00	0	36,675
77X49, 77X50, 77X51, 77X52.	Breast coil	EQ388	12,238.00	0	39,785
77X51, 77X52	CAD Workstation (CPU + Color Monitor)	ED056	14,829.62	0	36,675
85097	slide stainer, automated, hematology	EP121	8,649.43	1	34,559
92X71	Sleep mask	SK133	9.95	1	10,266
92X71, 92X73	mfERG and fERG electrodiagnostic unit	EQ390	102,400.00	1	25,602
92X71, 92X73	Contact lens electrode for mfERG and fERG.	EQ391	1,440.00	1	25,602
963X7, 963X8, 963X9, 96X10.	WAIS–IV Record Form	SK130	5.25	1	301,452
963X7, 963X8, 963X9, 96X10.	WAIS–IV Response Booklet #1	SK131	3.30	1	301,452
963X7, 963X8, 963X9, 96X10.	WMS–IV Response Booklet #2	SK132	2.00	1	301,452
963X7, 963X8, 963X9, 96X10.	Wechsler Adult Intelligence Scale—Fourth Edition (WAIS–IV) Kit (less forms).	EQ387	971.30	1	301,452
96X12	CANTAB Mobile (per single automated assessment).	ED055	2,800.00	1	0
990X1	heart failure patient physiologic monitoring equipment package.	EQ392	1,000.00	1	58
G0109	20x30 inch self-stick easel pad, white, 30 sheets/pad.	SK129	0.00	0	93,576
none	needle holder, Mayo Hegar, 6"	SC105	3.03	1	0

TABLE 17—PROPOSED CY 2019 NO PE REFINEMENTS

HCPCS	Description
10X11	Fna bx w/o img gdn ea addl.
10X13	Fna bx w/us gdn ea addl.
10X15	Fna bx w/fluor gdn ea addl.

TABLE 17—PROPOSED CY 2019 NO PE REFINEMENTS—Continued

HCPCS	Description
10X17	Fna bx w/ct gdn ea addl.
10X18	Fna bx w/mr gdn 1st les.
10X19	Fna bx w/mr gdn ea addl.

TABLE 17—PROPOSED CY 2019 NO PE REFINEMENTS—Continued

HCPCS	Description
332X0	Tcat impl wrls p-art prs snr.
332X5	Insj subq car rhythm mntr.
332X6	Rmvl subq car rhythm mntr.

TABLE 17—PROPOSED CY 2019 NO
PE REFINEMENTS—Continued

HCPCS	Description
33X05	Tcat insj/rpl perm ldl pm.
33X06	Tcat rmvl perm ldl pm.
36568	Insj picc <5 yr w/o imaging.
36569	Insj picc 5 yr+ w/o imaging.
36584	Compl rplcmt picc rs&i.
3853X	Open bx/exc inguinofem nodes.
49422	Remove tunneled ip cath.
50X39	Dilat xst trc ndurlgc px.
50X40	Dilat xst trc new access rcs.
53850	Prostatic microwave thermotx.
53852	Prostatic rf thermotx.
538X3	Trurl dstrj prst8 tiss rf vv.
57150	Treat vagina infection.
57160	Insert pessary/other device.
58110	Bx done w/colposcopy add-on.
65205	Remove foreign body from eye.
65210	Remove foreign body from eye.
67500	Inject/treat eye socket.
67505	Inject/treat eye socket.
67515	Inject/treat eye socket.
74485	Dilation utrtr/urt rs&i.
76514	Echo exam of eye thickness.
767X3	Use ea addl target lesion.
76942	Echo guide for biopsy.
77081	Dxa bone density/peripheral.
93668	Peripheral vascular rehab.
93XX1	Rem mntr wrls p-art prs snr.
95800	Slp stdy unattended.
95801	Slp stdy unatnd w/anal.
95806	Sleep study unatt&resp efft.
95970	Alys npgt w/o prgrmg.
95X83	Alys smpl cn npgt prgrmg.
95X84	Alys cplx cn npgt prgrmg.
95X85	Alys brn npgt prgrmg 15 min.
95X86	Alys brn npgt prgrmg addl 15.
96105	Assessment of aphasia.
96110	Developmental screen w/score.
96116	Neurobehavioral status exam.
96125	Cognitive test by hc pro.
96127	Brief emotional/behav asmt.
963X0	Devel tst phys/ghp 1st hr.
963X1	Devel tst phys/ghp ea addl.
963X2	Nubhvl xm phy/ghp ea addl hr.
963X3	Psycl tst eval phys/ghp 1st.
963X4	Psycl tst eval phys/ghp ea.
96X00	Ecog impltd brn npgt </30 d.
96X11	
990X0	Rem mntr physiol param setup.
99201	Office/outpatient visit new.
99211	Office/outpatient visit est.
994X7	Chrc care mgmt svc 30 min.
994X9	Rem physiol mntr 20 min mo.
G0166	Extrnl counterpulse, per tx.

I. Evaluation & Management (E/M) Visits

1. Background

a. E/M Visits Coding Structure

Physicians and other practitioners paid under the PFS bill for common office visits for evaluation and management (E/M) services under a relatively generic set of CPT codes (Level I HCPCS codes) that distinguish visits based on the level of complexity, site of service, and whether the patient is new or established. The CPT codes have three key components:

- History of Present Illness (History),
- Physical Examination (Exam) and
- Medical Decision Making (MDM).

These codes are broadly referred to as E/M visit codes. There are three to five E/M visit code levels, depending on site of service and the extent of the three components of history, exam and MDM. For example, there are three to four levels of E/M visit codes in the inpatient hospital and nursing facility settings, based on a relatively narrow degree of complexity in those settings. In contrast, there are five levels of E/M visit codes in the office or other outpatient setting based on a broader range of complexity in those settings.

Current PFS payment rates for E/M visit codes increase with the level of visit billed. As for all services under the PFS, the rates are based on the resources in terms of work (time and intensity), PE and malpractice expense required to furnish the typical case of the service. The current payment rates reflect typical service times for each code that are based on RUC recommendations.

In total, E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise approximately 20 percent of allowed charges for PFS services. Within these percentages, there is significant variation among specialties. According to Medicare claims data, E/M visits are furnished by nearly all specialties, but represent a greater share of total allowed services for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests. Generally, these practitioners include both primary care practitioners and specialists such as neurologists, endocrinologists and rheumatologists. Certain specialties, such as podiatry, tend to furnish lower level E/M visits more often than higher level E/M visits. Some specialties, such as dermatology and otolaryngology, tend to bill more E/M visits on the same day as they bill minor procedures.

Potential misvaluation of E/M codes is an issue that we have been carefully considering for several years. We have discussed at length in our recent PFS proposed and final rules that the E/M visit code set is outdated and needs to be revised and revalued (for example: 81 FR 46200 and 76 FR 42793). We have noted that this code set represents a high proportion of PFS expenditures, but has not been recently revalued to account for significant changes in the disease burden of the Medicare patient population and changes in health care practice that are underway to meet the Medicare population's health care needs (81 FR 46200). In the CY 2012 PFS

proposed rule, we proposed to refer all E/M codes to the RUC for review as potentially misvalued (76 FR 42793). Many commenters to that rule were concerned about the possible inadequacies of the current E/M coding and documentation structure to address evolving chronic care management and to support primary care (76 FR 73060 through 73064). We did not finalize our proposal to refer the E/M codes for RUC review at that time. Instead, we stated that we would allow time for consideration of the findings of certain demonstrations and other initiatives to provide improved information for the valuation of chronic care management, primary care, and care transitions. We stated that we would also continue to consider the numerous policy alternatives that commenters offered, such as separate E/M codes for established visits for patients with chronic disease versus a post-surgical follow-up office visit.

Many stakeholders continue to similarly express to us through letters, meetings, public comments in past rulemaking cycles, and other avenues, that the E/M code set is outdated and needs to be revised. For example, some stakeholders recommend an extensive research effort to revise and revalue E/M services, especially physician work inputs (CY 2017 PFS final rule, 81 FR 80227–80228). In recent years, we have continued to consider the best ways to recognize the significant changes in health care practice, especially innovations in the active management and ongoing care of chronically ill patients, under the PFS. We have been engaged in an ongoing, incremental effort to identify gaps in appropriate coding and payment.

b. E/M Documentation Guidelines

For coding and billing E/M visits to Medicare, practitioners may use one of two versions of the E/M Documentation Guidelines for a patient encounter, commonly referenced based on the year of their release: The “1995” or “1997” E/M Documentation Guidelines. These guidelines are available on the CMS website.³ They specify the medical record information within each of the three key components (such as number of body systems reviewed) that serves as support for billing a given level of E/M

³ See: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf>; <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf>; and the Evaluation and Management Services guide at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf>.

visit. The 1995 and 1997 guidelines are very similar to the guidelines that reside within the AMA's CPT codebook for E/M visits. For example, the core structure of what comprises or defines the different levels of history, exam, and medical decision-making are the same.

However, the 1995 and 1997 guidelines include extensive examples of clinical work that comprise different levels of medical decision-making and do not appear in the AMA's CPT codebook. Also, the 1995 and 1997 guidelines do not contain references to preventive care

that appear in the AMA's CPT codebook. We provide an example of how the 1995 and 1997 guidelines distinguish between level 2 and level 3 E/M visits in Table 18.

TABLE 18—KEY COMPONENT DOCUMENTATION REQUIREMENTS FOR LEVEL 2 VS. 3 E/M VISIT

Key component*	Level 2 (1995)	Level 3 (1995)	Level 2 (1997)	Level 3 (1997)
History (History of Present Illness or HPI).	Review of Systems (ROS) n/a.	Problem Pertinent ROS: Inquires about the system directly related to the problem(s) identified in the HPI.	No change from 1995	No change from 1995.
Physical Examination (Exam).	A limited examination of the affected body area or organ system.	A limited examination of the affected body area or organ system and other symptomatic or related organ system(s).	General multi-system exam: Performance and documentation of one to five elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of one to five elements.	General multi-system exam: Performance and documentation of at least six elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of at least six elements.
Medical Decision Making (MDM) Measured by:** 1. Problem—Number of diagnoses/treatment options. 2. Data—Amount and/or complexity of data to be reviewed. 3. Risk—Risk of complications and/or morbidity or mortality.	Straightforward: 1. Minimal 2. Minimal or no data review. 3. Minimal risk	Low complexity: 1. Limited. 2. Limited data review. 3. Low risk.	No change from 1995.	

* For certain settings and patient types, each of these three key components must be met or exceeded (for example, new patients; initial hospital visits). For others, only two of the three key components must be met or exceeded (for example, established patients, subsequent hospital or other visits).

** Two of three met or exceeded.

According to both Medicare claims processing manual instructions and CPT coding rules, when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter (or, in the case of inpatient E/M services, the floor time) the duration of the visit can be used as an alternative basis to select the appropriate E/M visit level (Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.C available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>; see also 2017 CPT Codebook Evaluation and Management Services Guidelines, page 10). Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.B states, “Instruct physicians to select the code for the service based upon the content of the service. The duration of the visit is an ancillary factor and does not control the level of the service to be billed unless more than 50 percent of the face-to-face time (for

non-inpatient services) or more than 50 percent of the floor time (for inpatient services) is spent providing counseling or coordination of care as described in subsection C.” Subsection C states that “the physician may document time spent with the patient in conjunction with the medical decision-making involved and a description of the coordination of care or counseling provided. Documentation must be in sufficient detail to support the claim.” The example included in subsection C further states, “The code selection is based on the total time of the face-to-face encounter or floor time, not just the counseling time. The medical record must be documented in sufficient detail to justify the selection of the specific code if time is the basis for selection of the code.”

Both the 1995 and 1997 E/M guidelines contain guidelines that address time, which state that “In the case where counseling and/or coordination of care dominates (more

than 50 percent of) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), time is considered the key or controlling factor to qualify for a particular level of E/M services.” The guidelines go on to state that “If the physician elects to report the level of service based on counseling and/or coordination of care, the total length of time of the encounter (face-to-face or floor time, as appropriate) should be documented and the record should describe the counseling and/or activities to coordinate care.”⁴

We note that other manual provisions regarding E/M visits that are cited in this proposed rule are housed separately within Medicare's Internet-Only Manuals, and are not contained within the 1995 or 1997 E/M documentation guidelines.

⁴ Page 16 of the 1995 E/M guidelines and page 48 of the 1997 guidelines.

In accordance with section 1862(a)(1)(A) of the Act, which requires services paid under Medicare Part B to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, medical necessity is a prerequisite to Medicare payment for E/M visits. The Medicare Claims Processing Manual states, “Medical necessity of a service is the overarching criterion for payment in addition to the individual requirements of a CPT code. It would not be medically necessary or appropriate to bill a higher level of evaluation and management service when a lower level of service is warranted. The volume of documentation should not be the primary influence upon which a specific level of service is billed. Documentation should support the level of service reported” (Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1A, available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>).

Stakeholders have long maintained that all of the E/M documentation guidelines are administratively burdensome and outdated with respect to the practice of medicine. Stakeholders have provided CMS with examples of such outdated material (on history, exam and MDM) that can be found within all versions of the E/M guidelines (the AMA’s CPT codebook, the 1995 guidelines and the 1997 guidelines). Stakeholders have told CMS that they believe the guidelines are too complex, ambiguous, fail to meaningfully distinguish differences among code levels, and are not updated for changes in technology, especially electronic health record (EHR) use. Prior attempts to revise the E/M guidelines were unsuccessful or resulted in additional complexity due to lack of stakeholder consensus (with widely varying views among specialties), and differing perspectives on whether code revaluation would be necessary under the PFS as a result of revising the guidelines, which contributed another layer of complexity to the considerations. For example, an early attempt to revise the guidelines resulted in an additional version designed for use by certain specialties (the 1997 version), and in CMS allowing the use of either the 1995 or 1997 versions for purposes of documentation and billing to Medicare. Another complication in revising the guidelines is that they are also used by many other payers, which have their own payment rules and audit

protocols. Moreover, stakeholders have suggested that there is sometimes variation in how Medicare’s own contractors (Medicare Administrative Contractors (MACs) interpret and apply the guidelines as part of their audit processes.

As previously mentioned, in recent years, some clinicians and other stakeholders have requested a major CMS research initiative to overhaul not only the E/M documentation guidelines, but also the underlying coding structure and valuation. Stakeholders have reported to CMS that they believe the E/M visit codes themselves need substantial updating and revaluation to reflect changes in the practice of medicine, and that revising the documentation guidelines without addressing the codes themselves simply preserves an antiquated framework for payment of E/M services.

Last year, CMS sought public comment on potential changes to the E/M documentation rules, deferring making any changes to E/M coding itself in order to immediately focus on revision of the E/M guidelines to reduce unnecessary administrative burden (82 FR 34078 through 34080). In the CY 2018 PFS final rule (82 FR 53163 through 53166), we summarized the public comments we received and stated that we would take that feedback into consideration for future rulemaking. In response to commenters’ request that we provide additional venues for stakeholder input, we held a listening session this year on March 18, 2018 (transcript and materials are available on the CMS website at <https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2018-03-21-Documents-Guidelines-and-Burden-Reduction.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>). We also sought input by participating in several listening sessions recently hosted by the Office of the National Coordinator for Health Information Technology (ONC) in the course of implementing section 4001(a) of the 21st Century Cures Act (Pub. L. 114–255). This provision requires the Department of Health and Human Services to establish a goal, develop a strategy, and make recommendations to reduce regulatory or administrative burdens relating to the use of EHRs. The ONC listening sessions sought public input on the E/M guidelines as one part of broader, related and unrelated burdens associated with EHRs.

Several themes emerged from this recent stakeholder input. Stakeholders commended CMS for undertaking to revise the E/M guidelines and

recommended a multi-year process. Many commenters advised CMS to obtain further input across specialties. They recommended town halls, open door forums or a task force that would come up with replacement guidelines that would work for all specialties over the course of several years. They urged CMS to proceed cautiously given the magnitude of the undertaking; past failed reform attempts by the AMA, CMS, and other payers; and the wide-ranging impact of any changes (for example, how other payers approach the issue).

We received substantially different recommendations by specialty. Based on this feedback, it is clear that any changes would have substantial specialty-specific impacts, both clinical and financial. Based on this feedback, it also seems that the history and exam portions of the guidelines are most significantly outdated with respect to current clinical practice.

A few stakeholders seemed to indicate that the documentation guidelines on history and exam should be kept in their current form. Many stakeholders believed they should be simplified or reduced, but not eliminated. Some stakeholders indicated that the documentation guidelines on history and exam could be eliminated altogether, and/or that documentation of these parts of an E/M visit could be left to practitioner discretion. We also heard from stakeholders that the degree to which an extended history and exam enables a given practitioner to reach a certain level of coding (and payment) varies according to their specialty. Many stakeholders advised CMS to increase reliance on medical decision-making (MDM) and time in determining the appropriate level of E/M visit, or to use MDM by itself, but many of these commenters believed that the MDM portions of the guidelines would need to be altered before being used alone. Commenters were divided on the role of time in distinguishing among E/M visit levels, and expressed some concern about potential abuse or inequities among more- or less-efficient practitioners. Some commenters expressed support for simplifying E/M coding generally into three levels such as low, medium and high, and potentially distinguishing those levels on the basis of time.

2. CY 2019 Proposed Policies

Having considered the public feedback to the CY 2018 PFS proposed rule (82 FR 53163 through 53166) and our other outreach efforts described above, we are proposing several changes to E/M visit documentation and

payment. The proposed changes would only apply to office/outpatient visit codes (CPT codes 99201 through 99215), except where we specify otherwise. We agree with commenters that we should take a step-wise approach to these issues, and therefore, we would limit initial changes to the office/outpatient E/M code set. We understand from commenters that there are more unique issues to consider for the E/M code sets used in other settings such as inpatient hospital or emergency department care, such as unique clinical and legal issues and the potential intersection with hospital Conditions of Participation (CoPs). We may consider expanding our efforts more broadly to address sections of the E/M code set beyond the office/outpatient codes in future years.

We wish to emphasize that, this year, we are including our proposed E/M documentation changes in a proposed rule due to the longstanding nature of our instruction that practitioners may use either the 1995 or 1997 versions of the E/M guidelines to document E/M visits billed to Medicare, the magnitude of the proposed changes, and the associated payment policy proposals that require notice and comment rulemaking. We believe our proposed documentation changes for E/M visits are intrinsically related to our proposal to alter PFS payment for E/M visits (discussed below), and the PFS payment proposal for E/M visits requires notice and comment rulemaking. We note that we are proposing a relatively broad outline of changes in this proposed rule, and we anticipate that many details related to program integrity and ongoing refinement would need to be developed over time through subregulatory guidance. This would afford flexibility and enable us to move nimbly and quickly make ongoing clarifications, changes and refinements in response to continued practitioner experience moving forward.

a. Lifting Restrictions Related to E/M Documentation

(i) Eliminating Extra Documentation Requirements for Home Visits

Medicare pays for E/M visits furnished in the home (a private residence) under CPT codes 99341 through 99350. The payment rates for these codes are slightly more than for office visits (for example, approximately \$30 more for a level 5 established patient, non-facility). The beneficiary need not be confined to the home to be eligible for such a visit. However, there is a Medicare Claims Processing Manual provision requiring that the medical record must document the medical

necessity of the home visit made in lieu of an office or outpatient visit (Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.14.1.B, available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>). Stakeholders have suggested that whether a visit occurs in the home or the office is best determined by the practitioner and the patient without applying additional rules. We agree, so we are proposing to remove the requirement that the medical record must document the medical necessity of furnishing the visit in the home rather than in the office. We welcome public comments on this proposal, including any potential, unintended consequences of eliminating this requirement. If we finalize this proposal in the CY 2019 PFS final rule, we would update the manual to reflect the change.

(ii) Public Comment Solicitation on Eliminating Prohibition on Billing Same-Day Visits by Practitioners of the Same Group and Specialty

The Medicare Claims Processing Manual states, “As for all other E/M services except where specifically noted, the Medicare Administrative Contractors (MACs) may not pay two E/M office visits billed by a physician (or physician of the same specialty from the same group practice) for the same beneficiary on the same day unless the physician documents that the visits were for unrelated problems in the office, off campus-outpatient hospital, or on campus-outpatient hospital setting which could not be provided during the same encounter” (Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.7.B, available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>).

This instruction was intended to reflect the idea that multiple visits with the same practitioner, or by practitioners in the same or very similar specialties within a group practice, on the same day as another E/M service would not be medically necessary. However, stakeholders have provided a few examples where this policy does not make sense with respect to the current practice of medicine as the Medicare enrollment specialty does not always coincide with all areas of medical expertise possessed by a practitioner—for example, a practitioner with the Medicare enrollment specialty of geriatrics may also be an endocrinologist. If such a practitioner was one of many geriatricians in the

same group practice, they would not be able to bill separately for an E/M visit focused on a patient’s endocrinological issue if that patient had another more generalized E/M visit by another geriatrician on the same day. Stakeholders have pointed out that in these circumstances, practitioners often respond to this instruction by scheduling the E/M visits on two separate days, which could unnecessarily inconvenience the patient. Given that the number and granularity of practitioner specialties recognized for purposes of Medicare enrollment continue to increase over time (consistent with the medical community’s requests), the value to the Medicare program of the prohibition on same-day E/M visits billed by physicians in the same group and medical specialty may be diminishing, especially as we believe it is becoming more common for practitioners to have multiple specialty affiliations, but would have only one primary Medicare enrollment specialty. We believe that eliminating this policy may better recognize the changing practice of medicine while reducing administrative burden. The impact of this proposal on program expenditures and beneficiary cost sharing is unclear. To the extent that many of these services are currently merely scheduled and furnished on different days in response to the instruction, eliminating this manual provision may not significantly increase utilization, Medicare spending and beneficiary cost sharing.

We are soliciting public comment on whether we should eliminate the manual provision given the changes in the practice of medicine or whether there is concern that eliminating it might have unintended consequences for practitioners and beneficiaries. We recognize that this instruction may be appropriate only in certain clinical situations, so we seek public comments on whether and how we should consider creating exceptions to, or modify this manual provision rather than eliminating it entirely. We are also requesting that the public provide additional examples and situations in which the current instruction is not clinically appropriate.

b. Documentation Changes for Office or Other Outpatient E/M Visits and Home Visits

(i) Providing Choices in Documentation—Medical Decision-Making, Time or Current Framework

Informed by comments and examples that we have received asserting that the current E/M documentation guidelines

are outdated with respect to the current practice of medicine, and in our efforts to simplify documentation for the purposes of coding E/M visit levels, we propose to allow practitioners to choose, as an alternative to the current framework specified under the 1995 or 1997 guidelines, either MDM or time as a basis to determine the appropriate level of E/M visit. This would allow different practitioners in different specialties to choose to document the factor(s) that matter most given the nature of their clinical practice. It would also reduce the impact Medicare may have on the standardized recording of history, exam and MDM data in medical records, since practitioners could choose to no longer document many aspects of an E/M visit that they currently document under the 1995 or 1997 guidelines for history, physical exam and MDM. While we initially considered reducing the number of key components that practitioners needed to document in choosing the appropriate level of E/M service to bill, feedback from the stakeholder community led us to believe that offering practitioners a choice to either retain the current framework or choose among new options that involve a reduced level of documentation would be less burdensome for practitioners, and would allow more stability for practitioners who may need time to prepare for any potential new documentation framework.

We wish to be clear that as part of this proposal, practitioners could use MDM, or time, or they could continue to use the current framework to document an E/M visit. In other words, we would be offering the practitioner the choice to continue to use the current framework by applying the 1995 or 1997 documentation guidelines for all three key components. However, our proposals on payment for office-based/outpatient E/M visits described later in this section would apply to all practitioners, regardless of their selected documentation approach. All practitioners, even those choosing to retain the current documentation framework, would be paid at the proposed new payment rate described in section II.I.2.c. of this proposed rule (one rate for new patients and another for established patients), and could also report applicable G-codes proposed in that section.

We also wish to be clear that we are proposing to retain the current CPT coding structure for E/M visits (along with creating new replacement codes for podiatry office/outpatient E/M visits) as described later in this section. Practitioners would report on the

professional claim whatever level of visit (1 through 5) they believe they furnished using CPT codes 99201–99215. We considered making an alternative proposal to adopt a single G-code to describe office/outpatient E/M visit levels 2 through 5 in conjunction with our proposal to establish a single PFS payment rate for those visits that is described later in this section. Because we believe the adoption of a reduced number of G-codes to describe the visit levels 2 through 5 might result in unnecessary disruption to current billing systems and practices, we are not proposing to modify the existing CPT coding structure for E/M visits. Since we are proposing to create a single rate under the PFS that would be paid for services billed using the current CPT codes for level 2 through 5 E/M visits, it would not be material to Medicare's payment decision which CPT code (of levels 2 through 5) is reported on the claim, except to justify billing a level 2 or higher visit in comparison to a level 1 visit (provided the visit itself was reasonable and necessary). We expect that, for record keeping purposes or to meet requirements of other payers, many practitioners would continue to choose and report the level of E/M visit they believe to be appropriate under the CPT coding structure.

Even though there would be no payment differential for E/M visits level 2 through 5, we believe we would still need to simplify and change our documentation requirements to better align with the current practice of medicine and eliminate unnecessary aspects of the current documentation framework. As a corollary to our proposal to adopt a single payment amount for office/outpatient E/M visit levels 2 through 5 (see section II.I.2.c. of this proposed rule), we propose to apply a minimum documentation standard where, for the purposes of PFS payment for an office/outpatient E/M visit, practitioners would only need to meet documentation requirements currently associated with a level 2 visit for history, exam and/or MDM (except when using time to document the service, see below). Practitioners could choose to document more information for clinical, legal, operational or other purposes, and we anticipate that for those reasons, they would continue generally to seek to document medical record information that is consistent with the level of care furnished. For purposes of our medical review, however, for practitioners using the current documentation framework or, as we are proposing, MDM, Medicare

would only require documentation to support the medical necessity of the visit and the documentation that is associated with the current level 2 CPT visit code.

For example, for a practitioner choosing to document using the current framework (1995 or 1997 guidelines), our proposed minimum documentation for any billed level of E/M visit from levels 2 through 5 could include: (1) A problem-focused history that does not include a review of systems or a past, family, or social history; (2) a limited examination of the affected body area or organ system; and (3) straightforward medical decision making measured by minimal problems, data review, and risk (two of these three). If the practitioner was choosing to document based on MDM alone, Medicare would only require documentation supporting straightforward medical decision-making measured by minimal problems, data review, and risk (two of these three).

Some commenters have suggested that the current framework of guidelines for the MDM component of visits would need to be changed before MDM could be relied upon by itself to distinguish visit levels. We propose to allow practitioners to rely on MDM in its current form to document their visit, and are soliciting public comment on whether and how guidelines for MDM might be changed in subsequent years.

As described earlier, we currently allow time or duration of visit to be used as the governing factor in selecting the appropriate E/M visit level, only when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter (or, in the case of inpatient E/M services, the floor time). Our proposal to allow practitioners the choice of using time to document office/outpatient E/M visits would mean that this time-based standard is not limited to E/M visits in which counseling and/or care coordination accounts for more than 50 percent of the face-to-face practitioner/patient encounter. Rather, the amount of time personally spent by the billing practitioner face-to-face with the patient could be used to document the E/M visit regardless of the amount of counseling and/or care coordination furnished as part of the face-to-face encounter.

Some commenters have raised concerns with reliance on time to distinguish visit levels, for example the potential for abuse, inequities among more- or less-efficient practitioners, and specialties for which time is less of a factor in determining visit complexity. Relying on time as the basis for

identifying the E/M visit level also raises the issue of what would be required by way of supporting documentation; for example, what amount of time should be documented, and whether the specific activities comprising the time need to be documented and to what degree. However, a number of stakeholders have suggested that, within their specialties, time is a good indicator of the complexity of the visit or patient, and requested that we allow practitioners to use time as the single factor in all E/M visits, not just when counseling or care coordination dominate a visit. We agree that for some practitioners and patients, time may be a good indicator of complexity of the visit, and are proposing to allow practitioners the option to use time as the single factor in selecting visit level and documenting the E/M visit, regardless of whether counseling or care coordination dominate the visit. If finalized, we would monitor the results of this proposed policy for any program integrity issues, administrative burden or other issues.

For practitioners choosing to support their coding and payment for an E/M visit by documenting the amount of time spent with the patient, we propose to require the practitioner to document the medical necessity of the visit and show the total amount of time spent by the billing practitioner face-to-face with the patient. We are soliciting public comment on what that total time should be for payment of the single, new rate for E/M visits levels 2 through 5. The typical time for our proposed new payment for E/M visit levels 2 through 5 is 31 minutes for an established patient and 38 minutes for a new patient, and we could use these times. These times are weighted averages of the intra-service times across the current E/M visit utilization. Accordingly, these times are higher than the current typical time for a level 2, 3 or 4 visit, but lower than the current typical time for a level 5 visit. We note that currently the PFS does not require the practitioner to spend or document a specified amount of time with a given patient in order to receive payment for an E/M visit, unless the visit is dominated by counseling/care coordination and, on that account, the practitioner is using time as the basis for code selection. The times for E/M visits and most other PFS services in the physician time files, which are used to set PFS rates, are typical times rather than requirements, and were recommended by the AMA RUC and then reviewed and either adopted or adjusted for Medicare through our usual

rate setting process as “typical,” but not strictly required.

One alternative is to apply the AMA’s CPT codebook provision that, for timed services, a unit of time is attained when the mid-point is passed,⁵ such that we would require documentation that at least 16 minutes for an established patient (more than half of 31 minutes) and at least 20 minutes for a new patient (more than half of 38 minutes) were spent face-to-face by the billing practitioner with the patient, to support making payment at the proposed single rate for visit levels 2 through 5 when the practitioner chooses to document the visit using time.

Another alternative is to require documentation that the typical time for the CPT code that is reported (which is also the typical time listed in the AMA’s CPT codebook for that code) was spent face-to-face by the billing practitioner with the patient. For example, a practitioner reporting CPT code 99212 (a level 2 established patient visit) would be required to document having spent a minimum of 10 minutes, and a practitioner reporting CPT code 99214 (a level 4 established patient visit) would be required to document having spent a minimum of 25 minutes. Under this approach, the total amount of time spent by the billing practitioner face-to-face with the patient would inform the level of E/M visit (of levels 2 through 5) coded by the billing practitioner. We note that in contrast to other proposed documentation approaches discussed above, this approach of requiring documentation of the typical time associated with the CPT visit code reported on the claim would introduce unique payment implications for reporting that code, especially when the time associated with the billed E/M code is the basis for reporting prolonged E/M services.

We are soliciting public comments on the use of time as a framework for documentation of office/outpatient E/M visits, and whether we should adopt any of these approaches or specify other requirements with respect to the proposed option for documentation using time.

In providing us with feedback, we ask commenters to take into consideration ways in which the time associated with, or required for, the billing of any add-on codes (especially the proposed prolonged E/M visit add-on code(s) described in section II.I.2.d.v. of this proposed rule) would intersect with the time spent for the base E/M visit, when the practitioner is documenting the E/M visit using only time. Currently, when

reporting prolonged E/M services, we expect the practitioner to exceed the typical time assigned for the base E/M visit code (also commonly referred to as the companion code). For example, in the CY 2017 PFS final rule (81 FR 80229), we expressed appreciation for the commenters’ suggestion to display the typical times associated with relevant services. We also discussed, and in response to those comments, decided to post a file annually that notes the times assumed to be typical for purposes of PFS ratesetting for practitioners to use as a reference in deciding whether time requirements for reporting prolonged E/M services are met. We stated that while these typical times are not required for a practitioner to bill the displayed base codes, we would expect that only time spent in excess of these times would be reported using a non-face-to-face prolonged service code. We are now proposing to formalize this policy in the case where a practitioner uses time to document a visit, since there would be a stricter time requirement associated with the base E/M code. Specifically, we propose that, when a practitioner chooses to document using time and also reports prolonged E/M services, we would require the practitioner to document that the typical time required for the base or “companion” visit is exceeded by the amount required to report prolonged services. See section II.I.2.d.v. of this proposed rule for further discussion of our proposal regarding reporting prolonged E/M services.

As we discuss further in this section of the proposed rule, we believe that allowing practitioners to choose the most appropriate basis for distinguishing among the levels of E/M visits and applying a minimum documentation requirement, together with reducing the payment variation among E/M visit levels, would significantly reduce administrative burden for practitioners, and would avoid the current need to make coding and documentation decisions based on codes and documentation guidelines that are not a good fit with current medical practice. The practitioner could choose to use MDM, time or the current documentation framework, and could also apply the proposed policies below regarding redundancy and who can document information in the medical record.

We heard from a few commenters on the CY 2018 PFS proposed rule that some practitioners rely on unofficial Marshfield clinic or other criteria to help them document E/M visit levels. These commenters conveyed that the

⁵ 2017 CPT Codebook Introduction, p.xv.

Marshfield “point system” is commonly used to supplement the E/M documentation guidelines, because of a lack of concrete criteria for certain elements of medical decision making in the 1995 and 1997 guidelines or in CPT guidance. We are soliciting public comment on whether Medicare should use or adopt any aspects of other E/M documentation systems that may be in use among practitioners, such as the Marshfield tool. We are interested in feedback as to whether the 1995 and 1997 guidelines contain adequate information for practitioners to use in documenting visits under our proposals, or whether these versions of the guidelines would need to be supplemented in any way.

We are seeking public comment on these proposals to provide practitioners choice in the basis for documenting E/M visits in an effort to allow for documentation alternatives that better reflect the current practice of medicine and to alleviate documentation burden. We are also interested in public comments on practitioners’ ability to avail themselves of these choices with respect to how they would impact clinical workflows, EHR templates, and other aspects of practitioner work. Commenters have requested that CMS not merely shift burden by implementing another framework that might avoid issues caused by the current guidelines, but that would be equally complex and burdensome. Our primary goal is to reduce administrative burden so that the practitioner can focus on the patient, and we are interested in commenters’ opinions as to whether our E/M visit proposals would, in fact, support and further this goal. We believe these proposals would allow practitioners to exercise greater clinical judgment and discretion in what they document, focusing on what is clinically relevant and medically necessary for the patient. While we propose to no longer apply much of the E/M documentation guidelines involving history, exam and, for those choosing to document based on time, documentation of medical decision-making, our expectation is that practitioners would continue to perform and document E/M visits as medically necessary for the patient to ensure quality and continuity of care. For example, we believe that it remains an important part of care for the practitioner to understand the patient’s social history, even though we would no longer require that history to be documented to bill Medicare for the visit.

(ii) Removing Redundancy in E/M Visit Documentation

Stakeholders have recently expressed that CMS should not require documentation of information in the billing practitioner’s note that is already present in the medical record, particularly with regard to history and exam. Currently, both the 1995 and 1997 guidelines provide such flexibility for certain parts of the history for established patients, stating, “A Review of Systems ‘ROS’ and/or a pertinent past, family, and/or social history ‘PFSH’ obtained during an earlier encounter does not need to be re-recorded if there is evidence that the physician reviewed and updated the previous information. This may occur when a physician updates his/her own record or in an institutional setting or group practice where many physicians use a common record. The review and update may be documented by:

- Describing any new ROS and/or PFSH information or noting there has been no change in the information; and
- Noting the date and location of the earlier ROS and/or PFSH.

Documentation Guidelines “DG”: The ROS and/or PFSH may be recorded by ancillary staff or on a form completed by the patient. To document that the physician reviewed the information, there must be a notation supplementing or confirming the information recorded by others (<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf>; <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf>).

We propose to expand this policy to further simplify the documentation of history and exam for established patients such that, for both of these key components, practitioners would only be required to focus their documentation on what has changed since the last visit or on pertinent items that have not changed, rather than re-documenting a defined list of required elements such as review of a specified number of systems and family/social history. Since medical decision-making can only be accurately formed upon a substantial basis of accurate and timely health information, and the CPT code descriptors for all E/M visits would continue to include the elements of history and exam, we expect that practitioners would still conduct clinically relevant and medically necessary elements of history and physical exam, and conform to the

general principles of medical record documentation in the 1995 and 1997 guidelines. However, practitioners would not need to re-record these elements (or parts thereof) if there is evidence that the practitioner reviewed and updated the previous information.

We are seeking comment on whether there may be ways to implement a similar provision for any aspects of medical decision-making, or for new patients, such as when prior data is available to the billing practitioner through an interoperable EHR or other data exchange. We believe there would be special challenges in realizing documentation efficiencies with new patients, since they may not have received exams or histories that were complete or relevant to the current complaint(s), and the information in the transferred record could be more likely to be incomplete, outdated or inaccurate.

Also, we propose that for both new and established patients, practitioners would no longer be required to re-enter information in the medical record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary. The practitioner could simply indicate in the medical record that they reviewed and verified this information. We wish to be clear that these proposed policy changes would be optional, where a practitioner could choose to continue to use the current framework, and the more detailed information could continue to be entered, re-entered or brought forward in documenting a visit, regardless of the documentation approach selected by the practitioner. Our goal is to allow practitioners more flexibility to exercise greater clinical judgment and discretion in what they document, focusing on what is clinically relevant and medically necessary for the patient. Our expectation is that practitioners would continue to periodically review and assess static or baseline historical information at clinically appropriate intervals.

(iii) Podiatry Visits

As described in greater detail in section II.L.2.d.iii. of this proposed rule, as part of our proposal to improve payment accuracy by creating a single PFS payment rate for E/M visit levels 2 through 5 (with one proposed rate for new patients and one proposed rate for established patients), we propose to create separate coding for podiatry visits that are currently reported as E/M office/outpatient visits. We propose that, rather than reporting visits under the general E/M office/outpatient visit

code set, podiatrists would instead report visits under new G-codes that more specifically identify and value their services. We propose to apply substantially the same documentation standards for these proposed new podiatry-specific codes as we propose above for other office/outpatient E/M visits.

If a practitioner chose to use time to document a podiatry office/outpatient E/M visit, we propose to apply substantially the same rules as those we are proposing for documenting on the basis of time for other office/outpatient E/M visits, discussed above. For practitioners choosing to use time to provide supporting documentation for the podiatry visit, we would require documentation supporting the medical necessity of the visit and showing the total amount of time spent by the billing practitioner face-to-face with the patient. We are soliciting public comment on what that total time would be for payment of the proposed new podiatry G-codes. The typical times for these proposed codes are 22 minutes for an established patient and 28 minutes for a new patient, and we could use these times. Alternatively, we could apply the AMA's CPT codebook provision that, for timed services, a unit of time is attained when the mid-point is passed,⁶ such that we would require documentation that at least 12 minutes for an established patient (more than half of 22 minutes) or at least 15 minutes for a new patient (more than half of 28 minutes) were spent face-to-face by the billing practitioner with the patient, to support making payment for these codes when the practitioner chooses to document the visit using time. We are soliciting comment on the use of time as a basis for documentation of our proposed podiatric E/M visit codes, and whether we should adopt any of these approaches or further specify other requirements with respect to this proposed option for podiatric practitioners to document their visits using time.

c. Minimizing Documentation Requirements by Simplifying Payment Amounts

As we have explained above, including in prior rulemaking, we believe that the coding, payment, and documentation requirements for E/M visits are overly burdensome and no longer aligned with the current practice of medicine. We believe the current set of 10 CPT codes for new and established office-based and outpatient E/M visits and their respective payment rates no

longer appropriately reflect the complete range of services and resource costs associated with furnishing E/M services to all patients across the different physician specialties, and that documenting these services using the current guidelines has become burdensome and out of step with the current practice of medicine. We have included the proposals described above to mitigate the burden associated with the outdated documentation guidelines for these services. To alleviate the effects and mitigate the burden associated with continued use of the outdated CPT code set, we are proposing to simplify the office-based and outpatient E/M payment rates and documentation requirements, and create new add-on codes to better capture the differential resources involved in furnishing certain types of E/M visits.

In conjunction with our proposal to reduce the documentation requirements for E/M visit levels 2 through 5, we are proposing to simplify the payment for those services by paying a single rate for the level 2 through 5 E/M visits. The visit level of the E/M service is tied to the documentation requirements in the 1995 and 1997 Documentation Guidelines for E/M Services, which may not be reflective of changes in technology or, in particular, the ways that electronic medical records have changed documentation and the patient's medical record. Additionally, current documentation requirements may not account for changes in care delivery, such as a growing emphasis on team based care, increases in the number of recognized chronic conditions, or increased emphasis on access to behavioral health care. However, based on the feedback we have received from stakeholders, it is clear to us that the burdens associated with documenting the selection of the level of E/M service arise from not only the documentation guidelines, but also from the coding structure itself. Like the documentation guidelines, the distinctions between visit levels reflect a reasonable assessment of variations in care, effort, and resource costs as identified and articulated several decades ago. We believe that the most important distinctions between the kinds of visits furnished to Medicare beneficiaries are not well reflected by the current E/M visit coding. Most significantly, we have understood from stakeholders that current E/M coding does not reflect important distinctions in services and differences in resources. At present, we believe the current payment for E/M visit levels, generally distinguished by common elements of

patient history, physical exam, and MDM, that may have been good approximations for important distinctions in resource costs between kinds of visits in the 1990s, when the CPT developed the E/M code set, are increasingly outdated in the context of changing models of care and information technologies.

As described earlier in this section, we are proposing to change the documentation requirements for E/M levels such that practitioners have the choice to use the 1995 guidelines, 1997 guidelines, time, or MDM to determine the E/M level. We believe that these proposed changes will better reflect the current practice of medicine and represent significant reductions in burdens associated with documenting visits using the current set of E/M codes.

In alignment with our proposed documentation changes, we are proposing to develop a single set of RVUs under the PFS for E/M office-based and outpatient visit levels 2 through 5 for new patients (CPT codes 99202 through 99205) and a single set of RVUs for visit levels 2 through 5 for established patients (CPT codes 99212 through 99215). While we considered creating new HCPCS G-codes that would describe the services associated with these proposed payment rates, given the wide and longstanding use of these visit codes by both Medicare and private payers, we believe it would have created unnecessary administrative burden to propose new coding. Therefore, we are instead proposing to maintain the current code set. Of the five levels of office-based and outpatient E/M visits, the vast majority of visits are reported as levels 3 and 4. In CY 2016, CPT codes 99203 and 99204 (or E/M visit level 3 and level 4 for new patients) made up around 32 percent and 44 percent, respectively, of the total allowed charges for CPT codes 99201–99205. In the same year, CPT codes 99213 and 99214 (or E/M visit level 3 and 4 for established patients) made up around 39 percent and 50 percent, respectively, of the allowed charges for CPT codes 99211–99215. If our proposals to simplify the documentation requirements and to pay a single PFS rate for new patient E/M visit levels 2 through 5 and a single rate for established patient E/M visit levels 2 through 5 are finalized, practitioners would still bill the CPT code for whichever level of E/M service they furnished and they would be paid at the single PFS rate. However, we believe that eliminating the distinction in payment between visit levels 2 through 5 will eliminate the need to audit against the visit levels, and therefore,

⁶ 2017 CPT Codebook Introduction, p.xv.

will provide immediate relief from the burden of documentation. A single payment rate will also eliminate the increasingly outdated distinction between the kinds of visits that are reflected in the current CPT code levels in both the coding and the associated documentation rules.

In order to set RVUs for the proposed single payment rate for new and established patient office/outpatient E/M visit codes, we are proposing to develop resource inputs based on the current inputs for the individual E/M codes, generally weighted by the frequency at which they are currently billed, based on the 5 most recent years of Medicare claims data (CY 2012 through CY 2017). Specifically, we are proposing a work RVU of 1.90 for CPT codes 99202–99205, a physician time of 37.79 minutes, and direct PE inputs that sum to \$24.98, each based on an average of the current inputs for the individual codes weighted by 5 years of accumulated utilization data. Similarly, we are proposing a work RVU of 1.22 for CPT codes 99212–99215, with a physician time of 31.31 minutes and direct PE inputs that sum to \$20.70. These inputs are based on an average of the inputs for the individual codes, weighted by volume based on utilization data from the past 5 years (CY 2012 through CY 2017). Tables 19 and 20 reflect the payment rates in dollars that would result from the approach described above were it to have been implemented for CY 2018. In other words, the dollar amounts in the charts below reflect how the changes we are proposing for CY 2019 would have impacted payment rates for CY 2018. Proposed RVUs for CY 2019 appear in addendum B of this proposed rule, available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>.

TABLE 19—PRELIMINARY COMPARISON OF PAYMENT RATES FOR OFFICE VISITS NEW PATIENTS

HCCPS code	CY 2018 non-facility payment rate	CY 2018 non-facility payment rate under the proposed methodology
99201	\$45	\$44
99202	76	135
99203	110
99204	167
99205	211

TABLE 20—PRELIMINARY COMPARISON OF PAYMENT RATES FOR OFFICE VISITS ESTABLISHED PATIENTS

HCCPS code	Current non-facility payment rate	Proposed non-facility payment rate
99211	\$22	\$24
99212	45	93
99213	74
99214	109
99215	148

While we believe that the proposed rates for E/M visit levels 2 through 5 represent the valuation of a typical E/M service, we also recognize that the current E/M code set itself does not appropriately reflect differences in resource costs between certain types of E/M visits. As a result, we believe that the way we currently value the resource costs for E/M services through the existing HCCPS CPT code set for office-based and outpatient E/M visits does not appropriately reflect the resources used in furnishing the range of E/M services that are provided through the current the practice of medicine. Based on stakeholder comments and examples and our review of the literature on E/M services, we have identified three types of E/M visits that differ from the typical E/M visit and are not appropriately reflected in the current office/outpatient E/M code set and valuation. Rather, these three types of E/M visits can be distinguished by the mode of care provided and, as a result, have different resource costs. The three types of E/M visits that differ from the typical E/M service are (1) separately identifiable E/M visits furnished in conjunction with a 0-day global procedure, (2) primary care E/M visits for continuous patient care, and (3) certain types of specialist E/M visits, including those with inherent visit complexity. We address each of these distinguishable visit types in the following proposals.

d. Recognizing the Resource Costs for Different Types of E/M Visits

Rather than maintain distinctions in services and payment that are based on the current E/M visit codes, we believe we can better capture differential resources costs and minimize reporting and documentation burden by proposing several corollary payment policies and ratesetting adjustments. These additional proposals better reflect the important distinctions between the kinds of visits furnished to Medicare beneficiaries, and would no longer require complex and burdensome billing and documentation rules to effectuate payment.

In response to the CY 2018 comment solicitation on burden reduction for E/M visits (82 FR 53163 through 53166), we received several comments that highlighted the inadequacy of the E/M code set to accurately pay for the resources associated with furnishing visits, particularly for primary care visits, and visits associated with treating patients with particular conditions for which there is not additional procedural coding. One commenter stated that the current structure and valuation of the E/M code set inadequately describes the range of services provided by different specialties, and in particular primary care services. This commenter noted that although the 10 office/outpatient E/M codes make up the bulk of the services reported by primary care practitioners, the valuation does not reflect their particular resource costs. Another commenter pointed out that for specialties that principally rely on E/M visit codes to bill for their professional services, the complex medical decision making and the intensity of their visits is not reflected in the E/M code set or documentation guidelines. Additionally, we believe that when a separately identifiable visit is furnished in conjunction with a procedure, that there are certain duplicative resource costs that are also not accounted for by current coding and payment.

Therefore, we are proposing the following adjustments to better capture the variety of resource costs associated with different types of care provided in E/M visits: (1) An E/M multiple procedure payment adjustment to account for duplicative resource costs when E/M visits and procedures with global periods are furnished together; (2) HCCPS G-code add-ons to recognize additional relative resources for primary care visits and inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits; (3) HCCPS G-codes to describe podiatric E/M visits; (4) an additional prolonged face-to-face services add-on G code; and (5) a technical modification to the PE methodology to stabilize the allocation of indirect PE for visit services (i) Accounting for E/M Resource Overlap between Stand-Alone Visits and Global Periods

Under the PFS, E/M services are generally paid in one of two ways: As standalone visits using E/M visit codes, or included in global procedural codes. In both cases, RVUs are allocated to the services to account for the estimated relative resources involved in furnishing professional E/M services. In the case of procedural codes with global periods,

the overall resource inputs reflect the costs of the E/M work considered to be typically furnished with the procedure. Therefore, the standalone E/M visit codes are not billable on the same day as the procedure codes unless the billing professional specifically indicates that the visit is separately identifiable from the procedure.

In cases where a physician furnishes a separately identifiable E/M visit to a beneficiary on the same day as a procedure, payment for the procedure and the E/M visit is based on rates generally developed under the assumption that these services are typically furnished independently. In CY 2017 PFS rulemaking, we noted that the current valuation for services with global periods may not accurately reflect much of the overlap in resource costs (81 FR 80209). We are particularly concerned that when a standalone E/M visit occurs on the same day as a 0-day global procedure, there are significant overlapping resource costs that are not accounted for. We believe that separately identifiable visits occurring on the same day as 0-day global procedures have resources that are sufficiently distinct from the costs associated with furnishing one of the 10 office/outpatient E/M visits to warrant payment adjustment. There are other existing policies under the PFS where we reduce payments if multiple procedures are furnished on the same day to the same patient. Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished to the same patient by the same physician on the same day, largely based on the presence of efficiencies in PE and pre- and post-surgical physician work. Effective January 1, 1995, the MPPR policy, with the same percentage reduction, was extended to nuclear medicine diagnostic procedures (CPT codes 78306, 78320, 78802, 78803, 78806, and 78807). In the CY 1995 PFS final rule with comment period (59 FR 63410), we indicated that we would consider applying the policy to other diagnostic tests in the future. In the CYs 2009 and 2010 PFS proposed rules (73 FR 38586 and 74 FR 33554, respectively), we stated that we planned to analyze nonsurgical services commonly furnished together (for example, 60 to 75 percent of the time) to assess whether an expansion of the MPPR policy could be warranted. MedPAC encouraged us to consider duplicative physician work, as well as PE, in any expansion of the MPPR policy. Finally, in the CY 2011 PFS final rule, CMS finalized the application of

the MPPR to always-therapy services on the justification that there was significant overlap in the PE portion of these services (75 FR 73233).

Using the surgical MPPR as a template, we are proposing that, as part of our proposal to make payment for the E/M levels 2 through 5 at a single PFS rate, we would reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier -25. We believe that the efficiencies associated with furnishing an E/M visit in combination with a same-day procedure are similar enough to those accounted for by the surgical MPPR to merit a reduction in the relative resources of 50 percent. We estimate based on CY 2017 Medicare claims data that applying a 50 percent MPPR to E/M visits furnished as separately identifiable services in the same day as a procedure would reduce expenditures under the PFS by approximately 6.7 million RVUs. To accurately reflect resource costs of the different types of E/M visits that we previously identified while maintaining work budget neutrality within this proposal, we are proposing to allocate those RVUs toward the values of the add-on codes that reflect the additional resources associated with E/M visits for primary care and inherent visit complexity, similar to existing policies. As we articulated in the CY 2012 PFS final rule with comment period, where the aggregate work RVUs within a code family change but the overall actual physician work associated with those services does not change, we make work budget neutrality adjustments to hold the aggregate work RVUs constant within the code family, while maintaining the relativity of values for the individual codes within that set (76 FR 73105).

(ii) Proposed HCPCS G-Code Add-Ons To Recognize Additional Relative Resources for Certain Kinds of Visits

The distribution of E/M visits is not uniform across medical specialties. We have found that certain specialists, like neurologists and endocrinologists, for example, bill higher level E/M codes more frequently than procedural specialists, such as dermatology. We believe this tendency reflects a significant and important distinction between the kinds of visits furnished by professionals whose treatment approaches are primarily reported using visit codes versus those professionals whose treatment approaches are

primarily reported using available procedural or testing codes. However, based on feedback we received from the medical professionals who furnish primary care and have visits with greater complexity, such as the comments cited above, we do not believe the current visit definitions and the associated documentation burdens are the most accurate descriptions of the variation in work. Instead, we believe these professionals have been particularly burdened by the documentation requirements given that so much of their medical treatment is described imperfectly by relatively generic visit codes.

Similarly stakeholders, such as the commenters responding to the CY 2018 PFS proposed rule, have articulated persuasively that visits furnished for the purpose of primary care also involve distinct resource costs. In developing this proposal, we consulted a variety of resources, including the American Academy of Family Physicians (AAFP) definition of primary care that states that the resource costs associated with furnishing primary care services particularly include time spent coordinating patient care, collaborating with other physicians, and communicating with patients (see <https://www.aafp.org/about/policies/all/primary-care.html>). Despite our efforts in recent years to pay separately for certain aspects of primary care services, such as through the chronic care management or the transitional care management services, the currently available coding still does not adequately reflect the full range of primary care services, nor does it allow payment to fully capture the resource costs involved in furnishing a face-to-face primary care E/M visit. We recognize that primary care services frequently involve substantial non-face-to-face work, and note that there is currently coding available to account for many of those resources, such as chronic care management (CCM), behavioral health integration (BHI), and prolonged non-face-to-face services. In light of the existing coding, this proposal only addresses the additional resources involved in furnishing the face-to-face portion of a primary care service. As the point of entry for many patients into the healthcare system, primary care visits frequently require additional time for communicating with the patient, patient education, consideration and review of the patient's medical needs. We believe the proposed value for the single payment rate for the E/M levels 2 through 5 new and established patient visit codes does

not reflect these additional resources inherent to primary care visits, as evidenced by the fact that primary care visits are generally reported using level 4 E/M codes. Therefore, to more accurately account for the type and intensity of E/M work performed in primary care-focused visits, we are proposing to create a HCPCS add-on G-code that may be billed with the generic E/M code set to adjust payment to account for additional costs beyond the typical resources accounted for in the single payment rate for the levels 2 through 5 visits.

We are proposing to create a HCPCS G-code for primary care services, GPC1X (Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an established patient evaluation and management visit)). As we believe a primary care visit is partially defined by an ongoing relationship with the patient, this code would describe furnishing a visit to an established patient. HCPCS code GPC1X can also be reported for other forms of face-to-face care management, counseling, or treatment of acute or chronic conditions not accounted for by other coding. We note that we believe the additional resources to address inherent complexity in E/M visits associated with primary care services are associated only with stand-alone E/M visits as opposed to separately identifiable visits furnished within the global period of a procedure. Separately identifiable visits furnished within a global period are identified on the claim using modifier –25, and would be subject to the MPPR. We note that we have created separate coding that describes non-face-to-face care management and coordination, such as CCM and BHI; however, these services describe non-face-to-face care and can be provided by any specialty so long as they meet the requirements for those codes. HCPCS code GPC1X is intended to capture the additional resource costs, beyond those involved in the base E/M codes, of providing face-to-face primary care services for established patients. HCPCS code GPC1X would be billed in addition to the E/M visit for an established patient when the visit includes primary care services. For HCPCS code GPC1X, we are proposing a work RVU of 0.07, physician time of 1.75 minutes, a PE RVU of 0.07, and an MP RVU of 0.01. This proposed valuation accounts for the additional resource costs associated with

furnishing primary care that distinguishes E/M primary care visits from other types of E/M visits, and maintains work budget neutrality across the office/outpatient E/M code set. Furthermore, the proposed add-on G-code for primary care-focused E/M services would help to mitigate potential payment instability that could result from our adoption of single payment rates that apply for E/M code levels 2 through 5. As this add-on G-code would account for the inherent resource costs associated with furnishing primary care E/M services, we anticipate that it would be billed with every primary care-focused E/M visit for an established patient. While we expect that this code will mostly be utilized by the primary care specialties, such as family practice or pediatrics, we are also aware that, in some instances, certain specialists function as primary care practitioners—for example, an OB/GYN or a cardiologist. Although the definition of primary care is widely agreed upon by the medical community and we intend for this G-code to account for the resource costs of performing those types of visits, regardless of Medicare enrollment specialty, we are also seeking comment on how best to identify whether or not a primary care visit was furnished particularly in cases where a specialist is providing those services. For especially complex patients, we also expect that it may be billed alongside the proposed new code for prolonged E/M services described later in this section. We are also seeking comment on whether this policy adequately addresses the deficiencies in CPT coding for E/M services in describing current medical practice, and concerns about the impact on payment for primary care and other services under the PFS. Given the broad scope of our proposals related to E/M services, we are seeking feedback on any unintended consequences of those proposals. We are also seeking comment on any other concerns related to primary care that we might consider for future rulemaking.

We are also proposing to create a HCPCS G-code to be reported with an E/M service to describe the additional resource costs for specialty professionals for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches we believe are generally reported using the level 4 and level 5 E/M visit codes rather than procedural coding. Due to these factors, the proposed single payment rate for E/M levels 2 through 5 visit codes would not necessarily reflect the

resource costs of those types of visits. Therefore, we are proposing to create a new HCPCS code GCG0X (Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit)). Given their billing patterns, we believe that these are specialties that apply predominantly non-procedural approaches to complex conditions that are intrinsically diffuse to multi-organ or neurologic diseases. While some of these specialties are surgical in nature, we believe these surgical specialties are providing increased non-procedural care of high complexity in the Medicare population. The high complexity of these services is reflected in the large proportion of level 4 and level 5 visits that we believe are reported by these specialties, and the extent to which E/M visits are a high proportion of these specialties' total allowed charges. Consequently, these are specialties for which the resource costs of the visits they typically perform are not fully captured in the proposed single payment rate for the levels 2 through level 5 office/outpatient visit codes. When billed in conjunction with standalone office/outpatient E/M visits for new and established patients, the combined valuation more accurately accounts for the intensity associated with higher level E/M visits. To establish a value for this add-on service to be applied with a standalone E/M visit, we are proposing a crosswalk to 75 percent of the work and time of CPT code 90785 (Interactive complexity), which results in a work RVU of 0.25, a PE RVU of 0.07, and an MP RVU of 0.01, as well as 8.25 minutes of physician time based on the CY 2018 valuation for CPT code 90785. Interactive complexity is an add-on code that may be billed when a psychotherapy or psychiatric service requires more resources due to the complexity of the patient. We believe that the proposed valuation for CPT code 90785 would be an accurate representation of the additional work associated with the higher level complex visits. We note that we believe the additional resources to address inherent complexity in E/M visits are associated with stand-alone E/M visits. Additionally, we acknowledge that resource costs for primary care are reflected with the proposed HCPCS code GPC1X, as opposed to the

proposed HCPCS code GCG0X. We note that there are additional codes available that include face-to-face and non-face-to-face work, depending on the code, that previously would have been considered part of an E/M visit, such as the codes for CCM, BHI, and CPT code 99483 (Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (*e.g.*, basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (*e.g.*, functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (*e.g.*, home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (*e.g.*, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver), which were developed to reflect the additional work of those practitioners furnishing primary care visits. Likewise, we are proposing that practitioners in the specialty of psychiatry would not use either add-on code because psychiatrists may utilize CPT code 90785 to describe work that might otherwise be reported with a level 4 or level 5 E/M visit.

We are seeking comment on both of these proposals.

(iii) Proposed HCPCS G-Code To Describe Podiatric E/M Visits

As described earlier, the vast majority of podiatric visits are reported using lower level E/M codes, with most E/M visits billed at a level 2 or 3, reflecting the type of work done by podiatrists as part of an E/M visit. Therefore, while the proposed consolidation of

documentation and payment for E/M code levels 2 through 5 is intended to better reflect the universal elements of E/M visits across specialties and patients, we believe that podiatric E/M visits are not accurately represented by the consolidated E/M structure. In order for payment to reflect the resource costs of podiatric visits, we are also proposing to create two HCPCS G-codes, HCPCS codes GPD0X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, new patient) and GPD1X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, established patient), to describe podiatric E/M services. Under this proposal, podiatric E/M services would be billed using these G-codes instead of the generic office/outpatient E/M visit codes (CPT codes 99201 through 99205 and 99211 through 99215). We propose to create these separate G-codes for podiatric E/M services to differentiate the resources associated with podiatric E/M visits rather than proposing a negative add-on adjustment relative to the proposed single payment rates for the generic E/M levels 2 through 5 codes. Therefore, we are proposing to create separate coding to describe these services, taking into account that most podiatric visits are billed as level 2 or 3 E/M codes. We based the coding structure and code descriptor on CPT codes 92004 (Ophthalmological services: Medical examination and evaluation with initiation of diagnostic and treatment program; comprehensive, new patient, 1 or more visits) and 92012 (Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient), which describe visits specific to ophthalmology. To accurately reflect payment for the resource costs associated with podiatric E/M visits, we are proposing a work RVU of 1.35, a physician time of 28.11 minutes, and direct PE inputs totaling \$22.53 for HCPCS code GPD0X, and a work RVU of 0.85, physician time of 21.60 minutes, and direct PE inputs totaling \$17.07 for HCPCS code GPD1X. These values are based on the average rate for the level 2 and 3 E/M codes (CPT codes 99201–99203 and CPT codes 99211–99212, respectively), weighted by podiatric volume.

(iv) Proposed Adjustment to the PE/HR Calculation

As we explain in section II.B. Determination of Practice Expense (PE) Relative Value Units (RVUs), of this

proposed rule, we generally allocate indirect costs for each code on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. Indirect expenses include administrative labor, office expense, and all other PEs that are not directly attributable to a particular service for a particular patient. Generally, the proportion of indirect PE allocated to a service is determined by calculating a PE/HR based upon the mix of specialties that bill for a service.

As described earlier, E/M visits comprise a significant portion of allowable charges under the PFS and are used broadly across specialties such that our proposed changes can greatly impact the change in payment at the specialty level and at the practitioner level. Our proposals seek to simplify payment for E/M visit levels 2 through 5, and to additionally take into consideration that there are inherent differences in primary care-focused E/M services and in more complex E/M services such that those visits involve greater relative resources, while seeking to maintain overall payment stability across specialties. However, establishing a single PFS rate for new and established patient E/M levels 2 through-5 would have a large and unintended effect on many specialties due to the way that indirect PE is allocated based on the mixture of specialties that furnish a service. The single payment rates proposed for E/M levels 2 through 5 cannot reflect the indirect PE previously allocated differentially across those 8 codes. Historically, a broad blend of specialties and associated PE/HR has been used in the allocation of indirect PE and MP RVUs to E/M services to determine payment rates for these services. As this proposal significantly alters the PE/HR allocation for the office/outpatient E/M codes and any previous opportunities for the public to comment on the data would not have applied to these kinds of E/M services, we do not believe it is in the public interest to allow the allocation of indirect PE to have such an outsized impact on the payment rates for this proposal. Due to the magnitude of the proposed coding and payment changes for E/M visits, it is unclear how the distribution of specialties across E/M services would change. We are concerned that such changes could produce anomalous results for indirect PE allocations since we do not yet know the extent to which specialties would utilize the proposed simplified E/M codes and proposed G-codes. In the past, when utilization data are not

available or do not accurately reflect the expected specialty mix of a new service, we have proposed to crosswalk the PE/HR value from another specialty (76 FR 73036). As such, we are proposing to create a single PE/HR value for E/M visits (including all of the proposed HCPCS G-codes discussed above) of approximately \$136, based on an average of the PE/HR across all specialties that bill these E/M codes, weighted by the volume of those specialties' allowed E/M services. We believe that this is consistent with the methodology used to develop the inputs for the proposed simplified E/M payment for the levels 2 through 5 E/M visit codes, and that, for purposes of consistency, the new PE/HR should be applied across the additional E/M codes. We believe a new PE/HR value would more accurately reflect the mix of specialties billing both the generic E/M code set and the add-on codes. If we finalize this proposal, we will consider revisiting the PE/HR after several years of claims data become available.

(v) Proposed HCPCS G-Code for Prolonged Services

Time is often an important determining factor in the level of care, which we consider in our proposal described earlier that physicians and other practitioners can use time as the basis for documenting and billing the appropriate level of E/M visit for purposes of Medicare payment. Currently there is inadequate coding to describe services where the primary resource of a service is physician time. CPT codes 99354 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting

requiring direct patient contact beyond the usual service; first hour (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)) and 99355 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)) describe additional time spent face-to-face with a patient and may be billed when the applicable amount of time exceeds the typical service time of the primary procedure.

Stakeholders have informed CMS that the "first hour" time threshold in the descriptor for CPT code 99354 is difficult to meet and is an impediment to billing these codes (81 FR 80228). In response to stakeholder feedback and as part of our proposal to implement a single payment rate for E/M visit levels 2 through 5 while maintaining payment accuracy across the specialties, we are proposing to create a new HCPCS code GPRO1 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)). Given that the physician time of HCPCS code GPRO1 is half of the physician time assigned to CPT code 99354, we are proposing a work RVU of 1.17, which is half the work RVU of CPT code 99354.

In order to estimate the potential impact of these proposed changes, we modeled the results of several options and examined the estimated resulting impacts in overall Medicare allowed charges by physician specialty. In order to isolate the potential impact of these changes from other concurrent proposed changes, we conducted this analysis largely using the code set, policies, and input data that we developed in establishing PFS rates for CY 2018. However, we used the suite of ratesetting programs that included several updates relevant for CY 2019 rulemaking. Consequently, we conducted our analysis regarding potential specialty-level impacts in order to identify the specialties with allowed charges most likely to be impacted by the potential change. We believe these estimates illustrate the magnitude of potential changes for certain physician specialties. However, because our modeling did not account for the full range of technical changes in the input data used in PFS ratesetting, the potential impacts for these isolated policies are relatively imprecise, especially compared to the specialty-level impacts displayed in section VII. of this proposed rule.

Tables 21, 22, and 23 show the estimated changes, for certain physician specialties, and isolated from other proposed changes, in expenditures for PFS services based on potential changes for E/M coding and payment. We note that we are making additional data available to the public to inform our modeling on our E/M coding and payment proposals, available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>.

TABLE 21—UNADJUSTED ESTIMATED SPECIALTY IMPACTS OF PROPOSED SINGLE RVU AMOUNTS FOR OFFICE/OUTPATIENT E/M 2 THROUGH 5 LEVELS

Specialty	Allowed charges (in millions)	Estimated potential impact of valuing levels 2–5 together, without additional adjustments
PODIATRY	\$2,022	12%.
DERMATOLOGY	3,525	7%.
HAND SURGERY	202	6%.
OTOLARNGOLOGY	1,220	5%.
ORTHOPEDIC SURGERY	3,815	4%.
ORAL/MAXILLOFACIAL SURGERY	57	4%.
COLON AND RECTAL SURGERY	168	Less than 3% estimated increase in overall payment.
OBSTETRICS/GYNECOLOGY	664	
OPTOMETRY	1,276	
PHYSICIAN ASSISTANT	2,253	
PLASTIC SURGERY	387	
ALLERGY/IMMUNOLOGY	240	Minimal change to overall payment.
ANESTHESIOLOGY	1,995	
AUDIOLOGIST	67	
CARDIAC SURGERY	313	

TABLE 21—UNADJUSTED ESTIMATED SPECIALTY IMPACTS OF PROPOSED SINGLE RVU AMOUNTS FOR OFFICE/OUTPATIENT E/M 2 THROUGH 5 LEVELS—Continued

Specialty	Allowed charges (in millions)	Estimated potential impact of valuing levels 2–5 together, without additional adjustments
CHIROPRACTOR	789	
CRITICAL CARE	334	
EMERGENCY MEDICINE	3,196	
FAMILY PRACTICE	6,382	
GASTROENTEROLOGY	1,807	
GENERAL PRACTICE	461	
GENERAL SURGERY	2,182	
INFECTIOUS DISEASE	663	
INTERVENTIONAL PAIN MGMT	839	
INTERVENTIONAL RADIOLOGY	362	
MULTISPECIALTY CLINIC/OTHER PHYS	141	
NEUROSURGERY	812	
NUCLEAR MEDICINE	50	
NURSE PRACTITIONER	3,586	
OPHTHALMOLOGY	5,542	
OTHER	30	
PATHOLOGY	1,151	
PHYSICAL MEDICINE	1,120	
PSYCHIATRY	1,260	
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	1,776	
RADIOLOGY	4,898	
THORACIC SURGERY	360	
UROLOGY	1,772	
VASCULAR SURGERY	1,132	
CARDIOLOGY	6,723	Less than 3% estimated decrease in overall payment.
INTERNAL MEDICINE	11,173	
NEPHROLOGY	2,285	
PEDIATRICS	64	
PULMONARY DISEASE	1,767	
GERIATRICS	214	
RHEUMATOLOGY	559	
NEUROLOGY	1,565	
HEMATOLOGY/ONCOLOGY	1,813	
ENDOCRINOLOGY	482	
TOTAL	93,486	0.

Table 21 characterizes the estimated overall impact for certain physician specialties, of establishing single payment rates for the new and established patient E/M code levels 2 through 5, without any of the additional coding or proposed payment adjustments, including the estimated

percentage change for the specialties with an estimated increase or decrease in payment greater than 3 percent. Those specialties that tend to bill lower level E/M visits would benefit the most from the proposed change to single PFS payment rates, while those specialties that tend to bill more higher level E/M

visits would see the largest decreases in payment with the change to a single PFS rate. The single payment rate for E/M code levels 2 through 5 would benefit podiatry the most because, due to the nature of most podiatric E/M visits, they tend to bill only level 2 and 3 E/M visits.

TABLE 22—SPECIALTY SPECIFIC IMPACTS INCLUDING PAYMENT ACCURACY ADJUSTMENTS

Specialty	Allowed charges (in millions)	Estimated potential impact of valuing levels 2–5 together, with additional adjustments
OBSTETRICS/GYNECOLOGY	\$664	4%.
NURSE PRACTITIONER	3,586	3%.
HAND SURGERY	202	Less than 3% estimated increase in overall payment.
INTERVENTIONAL PAIN MGMT	839	
OPTOMETRY	1,276	
PHYSICIAN ASSISTANT	2,253	
PSYCHIATRY	1,260	
UROLOGY	1,772	
ANESTHESIOLOGY	1,995	Minimal change to overall payment.
CARDIAC SURGERY	313	
CARDIOLOGY	6,723	
CHIROPRACTOR	789	

TABLE 22—SPECIALTY SPECIFIC IMPACTS INCLUDING PAYMENT ACCURACY ADJUSTMENTS—Continued

Specialty	Allowed charges (in millions)	Estimated potential impact of valuing levels 2–5 together, with additional adjustments
COLON AND RECTAL SURGERY	168	
CRITICAL CARE	334	
EMERGENCY MEDICINE	3,196	
ENDOCRINOLOGY	482	
FAMILY PRACTICE	6,382	
GASTROENTEROLOGY	1,807	
GENERAL PRACTICE	461	
GENERAL SURGERY	2,182	
GERIATRICS	214	
INFECTIOUS DISEASE	663	
INTERNAL MEDICINE	11,173	
INTERVENTIONAL RADIOLOGY	362	
MULTISPECIALTY CLINIC/OTHER PHYS	141	
NEPHROLOGY	2,285	
NEUROSURGERY	812	
NUCLEAR MEDICINE	50	
OPHTHALMOLOGY	5,542	
ORAL/MAXILLOFACIAL SURGERY	57	
ORTHOPEDIC SURGERY	3,815	
OTHER	30	
PATHOLOGY	1,151	
PEDIATRICS	64	
PHYSICAL MEDICINE	1,120	
PLASTIC SURGERY	387	
RADIOLOGY	4,898	
THORACIC SURGERY	360	
VASCULAR SURGERY	1,132	
ALLERGY/IMMUNOLOGY	240	Less than 3% estimated decrease in overall payment.
AUDIOLOGIST	67	
HEMATOLOGY/ONCOLOGY	1,813	
NEUROLOGY	1,565	
OTOLARNGOLOGY	1,220	
PULMONARY DISEASE	1,767	
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	1,776	
RHEUMATOLOGY	559	–3.
DERMATOLOGY	3,525	–4.
PODIATRY	2,022	–4.
TOTAL	93,486	0.

Table 22 characterizes the estimated overall impact for certain physician specialties, including the proposed adjustments have been made to reflect the distinctions in resource costs among certain types of E/M visits. In other words, Table 22 shows the proposed impacts of adopting the proposed single payment rates for new and established patient E/M visit levels 2 through 5, the application of a MPPR to E/M visits when furnished by the same practitioner (or practitioner in the same practice) on the same-day as a global procedure code, the add-on G-codes for primary care-focused services and inherent visit complexity, and the technical adjustments to the PE/HR value. Table 22 includes the estimated percentage change for the specialties with an estimated increase or decrease in payment greater than three percent. In our modeling, we assumed E/M visits for specialties that provide a significant

portion of primary care like family practice, internal medicine, pediatrics and geriatrics utilized the G-code for visit complexity inherent to evaluation and management associated with primary medical care services with every office/outpatient visit furnished. Also for the purposes of our modeling, we assumed that specialties including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care utilized the G-code for visit complexity inherent to evaluation and management with every office/outpatient E/M visit. Table 22 does not include the impact of the use of the additional prolonged services code. The specialties that we estimate would experience a decrease in payments are those that bill a large portion of E/M visits on the same day as procedures,

and would see a reduction based on the application of the MPPR adjustments. Some of these specialties, such as allergy/immunology and cardiology are also negatively impacted by the proposed single payment rates themselves, although not to the same degree as they would have been without any adjustments to provide alternate coding to reflect their resource costs, as illustrated in Table 21. The specialties that we estimate will see an increase in payments from these proposals, like psychiatry, nurse practitioner, and endocrinology, are seeing payment increases due to a combination of the single payment rate and the add-on codes for inherent visit complexity.

As an example, in CY 2018, a physician would bill a level 4 E/M visit and document using the existing documentation framework for a level 4 E/M visit. Their payment rate would be approximately \$109 in the office setting.

If these proposals are finalized, the physician would bill the same visit code for a level 4 E/M visit, documenting the visit according to the minimum documentation requirements for a level 2 E/M visit and/or based on their choice of using time, MDM, or the 1995 or 1997 guidelines, plus either of the proposed add-on codes (HCPCS codes GPC1X or GCG0X) depending on the type of patient care furnished, and could bill one unit of the proposed prolonged services code (HCPCS code GPRO1) if they meet the time threshold for this code. The combined payment rate for the generic E/M code and HCPCS code GPRO1 would be approximately \$165 with HCPCS code GPC1X and approximately \$177 with HCPCS code GCG0X.

We welcome comments on all of these proposals.

(vi) Alternatives Considered

We considered a number of other options for simplifying coding and payment for E/M services to align with the proposed reduction in documentation requirements and better account for the resources associated with inherent complexity, visit complexity, and visits furnished on the same day as a 0-day global procedure. For example, we considered establishing single payment rates for new and established patients for combined E/M visit levels 2 through 4, as opposed to combined E/M visit levels 2 through 5. This option would have retained a separately valued payment rate for level 5 visits that would be reserved for the most complex visits or patients. However, maintaining a separately valued payment rate for this higher level visit based on the current CPT code definition has the consequence of preserving some of the current coding distinctions within the billing systems. Ultimately we believe that providing for two levels of payment and documentation (setting aside level 1 visits which are primarily visits by clinical staff) relieves more burden than three levels, and that two levels plus the proposed add-on coding more accurately captures the differential resource costs involved in furnishing E/M services to all patients. If we retained a coding scheme involving three or more levels of E/M visits, it would not be appropriate to apply a minimum documentation requirement as we propose to do. We would need to develop documentation requirements unique to each of the higher level visits. There would be a greater need for program integrity mechanisms to prevent upcoding and ensure that practitioners who chose to report the

highest level visit justified their selection of code level. We could still simplify the documentation requirements for E/M visits relative to the current framework, but would need a more extensive, differential documentation framework than what we propose in this rule, in order to distinguish among visit levels. We are interested in stakeholder input on the best number of E/M visit levels and how to best achieve a balance between number of visit levels and simpler, updated documentation rules. We are seeking input as to whether these two aspects of our proposals together can reduce burden and ensure accurate payment across the broad range of E/M visits, including those for complex and high need beneficiaries.

TABLE 23—UNADJUSTED ESTIMATED SPECIALTY IMPACTS OF SINGLE PFS RATE FOR OFFICE/OUTPATIENT E/M LEVELS 2 THROUGH 4

Specialty	Allowed charges (millions)	Impact (percent)
Podiatry	\$2,022	10
Dermatology ...	3,525	6
Hand Surgery	202	5
Oral/Maxillo-facial Surgery	57	4
Otolaryngology	1,220	4
Cardiology	6,723	-3
Hematology/Oncology	1,813	-3
Neurology	1,565	-3
Rheumatology	559	-6
Endocrinology	482	-8

Note: All other specialty level impacts were within +/- 3%.

Table 23 shows the specialties that would experience the greatest increase or decrease by establishing single payment rates for E/M visit levels 2 through 4, while maintaining the value of the level 1 and the level 5 E/M visits. The specialty level impacts are similar to those in Table 21 as the specialties that bill more higher level visits do not benefit by maintaining a distinct payment for the level 5 visit as much as they experience a reduction in the rate for a level 4 visit. Similarly, the specialties that bill predominantly lower level visits would still benefit disproportionately to the increase in rate for the level 2 and level 3 visits.

Section 101(f) of the MACRA, enacted on April 16, 2015, added a new subsection (r) under section 1848 of the Act entitled Collaborating with the Physician, Practitioner, and Other Stakeholder Communities to Improve Resource Use Measurement. Section 1848(r) of the Act requires the

establishment and use of classification code sets: Care episode and patient condition groups and codes; and patient relationship categories and codes. As described in the CY 2018 PFS final rule, we finalized use of Level II HCPCS Modifiers as the patient relationship codes and finalized that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, should include the applicable patient relationship codes, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). We noted that for CY 2018, reporting of the patient relationship modifiers would be voluntary and the use and selection of the modifiers would not be a condition of payment (82 FR 53234). The patient relationship codes are as follows: X1: Continuous/broad; X2: Continuous/focused; X3: Episodic/focused; X4: Episodic/broad; and X5: Only as ordered by another physician. These codes are to be used to help define and distinguish the relationship and responsibility of a clinician with a patient at the time of furnishing an item or service, facilitate the attribution of patients and episodes to one or more clinicians, and to allow clinicians to self-identify their patient relationships.

We considered proposing the use of these codes to adjust payment for E/M visits to the extent that these codes are indicative of differentiated resources provided in E/M visits, and we considered using these codes as an alternative to the proposed use of G-codes to reflect visit complexity inherent to evaluation and management in primary care and certain other specialist services, as a way to more accurately reflect the resource costs associated with furnishing different kinds of E/M visits. We are seeking comment on this alternative. We are particularly interested in whether the modifiers would accurately reflect the differences between resources for E/M visits across specialties and would therefore be useful to adjust payment differentially for the different types of E/M visits that we previously identified.

e. Emergency Department and Other E/M Visit Settings

As we mentioned above, the E/M visit code set is comprised of individual subsets of codes that are specific to various clinical settings including office/outpatient, observation, hospital inpatient, emergency department, critical care, nursing facility, domiciliary or rest home, and home services. Some of these code subsets have three E/M levels of care, while

others have five. Some of these E/M code subsets distinguish among levels based heavily on time, while others do not. Recent public comments have asserted that some E/M code subsets intersect more heavily than others with hospital conditions of participation (CoP). For example, the American Psychiatric Association (APA) submitted a letter to CMS indicating that Medicare requires specific documentation in the medical record as part of the CoPs for inpatient psychiatric facilities. The APA believed that the required initial psychiatric evaluation for inpatients currently closely follows the E/M criteria for CPT codes 99221–99223, which are the codes that would be used to bill for these services. The APA stated that any changes in these E/M codes, without corresponding changes in the CoPs, could lead to the unintended consequence of adding to the burden of documentation by essentially requiring two different sets of data or areas of focus to be included, or two different documentation formats being required.

Regarding emergency department visits (CPT codes 99281–99285), we received more recent feedback through our coordinated efforts with ONC this year, emphasizing that these codes may benefit from a coding or payment compression into fewer levels of codes, or that documentation rules may need to be reduced or altered. However, in public comments to the CY 2018 PFS proposed rule, commenters noted several issues unique to the emergency department setting that we believe require further consideration. For example, commenters stated that intensity, and not time, is the main determinant of code level in emergency departments. They requested that CMS use caution in changing required elements for documentation so that medical information used for legal purposes (for example, meeting the prudent layperson standard) is not lost. They urged caution and requested that CMS not immediately implement any major changes. They recommended refocusing documentation on presenting conditions and medical decision-making. Some commenters were supportive of leaving it largely to the discretion of individual practitioners to determine the degree to which they should perform and document the history and physical exam in the emergency department setting. Other commenters suggested that CMS encourage use of standardized guidelines and minimum documentation requirements to facilitate post-treatment evaluation, as

well as analysis of records for various clinical, legal, operational and other purposes. The commenters discussed the importance of extensive histories and exams in emergency departments, where usually there is no established relationship with the patient and differential diagnosis is critical to rule out many life-threatening conditions. They were cognizant of the need for a clear record of services rendered and the medical necessity for each service, procedure, diagnostic test, and MDM performed for every patient encounter.

In addition, although the RUC is in the process of revaluing this code set, some commenters stated that the main issue is not that the emergency department visit codes themselves are undervalued. Rather, these commenters believed that a greater percentage of emergency department visits are at a higher acuity level, yet payers often do not pay at a higher level of care and the visit is often inappropriately down-coded based on retrospective review. These commenters believed that the documentation needed to support a higher level of care is too burdensome or subjective. In addition, it seems that policy proposals regarding emergency department visits billed by physicians might best be coordinated with parallel changes to payment policy for facility billing of these codes, which would require more time and analyses.

Accordingly, we are not proposing any changes to the emergency department E/M code set or to the E/M code sets for settings of care other than office-based and outpatient settings at this time. However, we are seeking public comment on whether we should make any changes to it in future years, whether by way of documentation, coding, and/or payment and, if so, what the changes should be.

Consistent with public feedback to date, we are taking a step-wise approach and limiting our policy proposals this year to the office/outpatient E/M code set (and the limited proposal above regarding documentation of medical necessity for home visits in lieu of office visits). We may consider expanding our efforts more broadly to additional sections of the E/M visit code set in future years, and are seeking public comment broadly on how we might proceed in this regard.

f. Proposed Implementation Date

We propose that these proposed E/M visit policies would be effective January 1, 2019. However, we are sensitive to commenters' suggestions that we should consider a multi-year process and proceed cautiously, allowing adequate time to educate practitioners and their

staff; and to transition clinical workflows, EHR templates, institutional processes and policies (such as those for provider-based practitioners), and other aspects of practitioner work that would be impacted by these policy changes. Our proposed documentation changes for office/outpatient E/M visits would be optional, and practitioners could choose to continue to document these visits using the current framework and rules, which may reduce the need for a delayed implementation. Nevertheless, practitioners who choose a new documentation framework may need time to deploy it. A delayed implementation date for our documentation proposals would also allow the AMA time to develop changes to the CPT coding definitions and guidance prior to our implementation, such as changes to MDM or code definitions that we could then consider for adoption. It would also allow other payers time to react and potentially adjust their policies. Accordingly, we are seeking comment on whether a delayed implementation date, such as January 1, 2020, would be appropriate for our proposals.

J. Teaching Physician Documentation Requirements for Evaluation and Management Services

1. Background

Per 42 CFR part 415, subpart D, Medicare Part B makes payment under the PFS for teaching physician services when certain conditions are met, including that medical record documentation must reflect the teaching physician's participation in the review and direction of services performed by residents in teaching settings. Under § 415.172(b), for certain procedural services, the participation of the teaching physician may be demonstrated by the notes in the medical records made by a physician, resident, or nurse; and for E/M visits, the teaching physician is required to personally document their participation in the medical record. We received stakeholder feedback suggesting that documentation requirements for E/M services furnished by teaching physicians are burdensome and duplicative of notations that may have previously been included in the medical records by residents or other members of the medical team.

2. Proposed Implementation

We are proposing to revise our regulations to eliminate potentially duplicative requirements for notations that may have previously been included in the medical records by residents or

other members of the medical team. These proposed changes are intended to align and simplify teaching physician E/M service documentation requirements. We believe these proposed changes will reduce burden and duplication of effort for teaching physicians. We are proposing to amend § 415.172(b) to provide that, except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document that the teaching physician was present at the time the service is furnished. Additionally, the revised paragraph would specify that the presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by a physician, resident, or nurse. We are also proposing to amend § 415.174, by deleting paragraph (a)(3)(v) which currently requires the teaching physician to document the extent of their participation in the review and direction of the services furnished to each beneficiary, and adding new paragraph (a)(6), to provide that the medical record must document the extent of the teaching physician's participation in the review and direction of services furnished to each beneficiary, and that the extent of the teaching physician's participation may be demonstrated by the notes in the medical records made by a physician, resident, or nurse.

K. Solicitation of Public Comments on the Low Expenditure Threshold Component of the Applicable Laboratory Definition Under the Medicare Clinical Laboratory Fee Schedule (CLFS)

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for clinical diagnostic laboratory tests (CDLTs) under the CLFS. The CLFS final rule titled, Medicare Clinical Diagnostic Laboratory Tests Payment System final rule (CLFS final rule), published in the **Federal Register** on June 23, 2016, implemented section 1834A of the Act. Under the CLFS final rule (81 FR 41036), "reporting entities" must report to CMS during a "data reporting period" "applicable information" (that is, certain private payer data) collected for a "data collection period" for their component

"applicable laboratories." In general, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected for the 6-month data collection period and reported to us in the 3-month data reporting period, and is equal to the weighted median of the private payor rates for the CDLT.

An applicable laboratory is defined at § 414.502, in part, as an entity that is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA) definition at § 493.2) that bills Medicare Part B under its own National Provider Identifier (NPI). In addition, an applicable laboratory is an entity that receives more than 50 percent of its Medicare revenues during a data collection period from the CLFS and/or the PFS. We refer to this component of the applicable laboratory definition as the "majority of Medicare revenues threshold." The definition of applicable laboratory also includes a "low expenditure threshold" component, which requires an entity to receive at least \$12,500 of its Medicare revenues from the CLFS in a data collection period for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs).

We established \$12,500 as the low expenditure threshold because we believed it achieved a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT, and minimizing the reporting burden for laboratories that receive a relatively small amount of revenues under the CLFS. In the CLFS final rule (81 FR 41051), we estimated that 95 percent of physician office laboratories and 55 percent of independent laboratories would not be required to report applicable information under our low expenditure threshold criterion. Although we substantially reduced the number of laboratories qualifying as applicable laboratories (that is, approximately 5 percent of physician office laboratories and approximately 45 percent of independent laboratories) we estimated that the percentage of Medicare utilization would remain high. That is, approximately 5 percent of physician office laboratories would account for approximately 92 percent of CLFS spending on physician office laboratories and approximately 45 percent of independent laboratories would account for approximately 99 percent of CLFS spending on independent laboratories (81 FR 41051).

Recently, we have heard from some laboratory stakeholders that the low expenditure threshold excludes most physician office laboratories and many

small independent laboratories from reporting applicable information, and that by excluding so many laboratories, the payment rates under the new private payor rate-based CLFS reflects incomplete data, and therefore, inaccurate CLFS pricing. However, it is our understanding that physician offices are generally not prepared to identify, collect, and report each unique private payor rate from each private payor for each laboratory test code on the CLFS and the volume associated with each unique private payor rate. As such, we believe revising the low expenditure threshold so that more physician office laboratories are required to report applicable information would be a very significant administrative burden on physician's offices. We also believe that increasing participation from physician office laboratories would have minimal overall impact on payment rates given that the weighted median of private payor rates is dominated by the laboratories with the largest test volume.

However, we recognize from stakeholders that some physician office laboratories and small independent laboratories that are not applicable laboratories because they do not meet the current low expenditure threshold may still want to report applicable information, despite the administrative burden associated with qualifying as an applicable laboratory. Therefore, we are seeking public comments on reducing the low expenditure threshold by 50 percent, from \$12,500 to \$6,250, in CLFS revenues during a data collection period. Since more physician office laboratories would meet the low expenditure threshold, we would expect such an approach to increase the level of applicable information reported by physician office laboratories and small independent laboratories. We are seeking public comments regarding the potential administrative burden on physician office laboratories and small independent laboratories that would result from reducing the low expenditure threshold. We are also soliciting public comments on an approach that would increase the low expenditure threshold by 50 percent, from \$12,500 to \$18,750, in CLFS revenues received in a data collection period. Since fewer physician office laboratories and small independent laboratories would meet the definition of applicable laboratory, we would expect such an approach to result in a decreased level of applicable information reported. For a complete discussion of our solicitation of comments on the low expenditure threshold component of the definition

of applicable laboratory under the Medicare CLFS, we refer readers to section III.A. of this proposed rule.

L. GPCI Comment Solicitation

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPICs at least every 3 years. Section 1848(e)(1)(D) of the Act requires us to establish the GPICs using the most recent data available. The last GPCI update was implemented in CY 2017; therefore, we are required to review and make any necessary revisions to the GPICs for CY 2020. Please refer to the CY 2017 PFS final rule with comment period for a discussion of the last GPCI update (81 FR 80261 through 80270). Some stakeholders have continued to express concerns regarding some of the data sources used in developing the indices for PFS geographic adjustment purposes, specifically that we use residential rent data as a proxy for commercial rent in the rent index component of the PE GPCI—that is, the data that are used to develop the office rent component of the PE GPCI. We will continue our efforts to identify a nationally representative commercial rent data source that could be made available to CMS. In support of that effort, we are particularly interested in, and seek comments regarding potential sources of commercial rent data for potential use in the next GPCI update for CY 2020.

M. Therapy Services

1. Repeal of the Therapy Caps and Limitation To Ensure Appropriate Therapy

Section 50202 of the Bipartisan Budget Act of 2018 (BBA of 2018) amended section 1833(g) of the Act, effective January 1, 2018, to repeal the application of the Medicare outpatient therapy caps and the therapy cap exceptions process while retaining and adding limitations to ensure therapy services are furnished when appropriate. Section 50202 also adds section 1833(g)(7)(A) of the Act to require that after expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the previous therapy cap amounts, all therapy suppliers and providers must continue to use an appropriate modifier such as the KX modifier on claims for subsequent services in order for Medicare to pay for the services. We implemented this provision by continuing to use the KX modifier. By applying the KX modifier to the claim, the therapist or therapy provider is confirming that the services are medically necessary as justified by

appropriate documentation in the medical record. Just as with the incurred expenses for the prior therapy cap amounts, there is one amount for physical therapy (PT) and speech language pathology (SLP) services combined and a separate amount for occupational therapy (OT) services. These KX modifier threshold amounts are indexed annually by the Medicare Economic Index (MEI). For CY 2018, this KX modifier threshold amount is \$2,010 for PT and SLP services combined, and \$2,010 for OT. After the beneficiary's incurred expenditures for outpatient therapy services exceed the KX modifier threshold amount for the year, claims for outpatient therapy services without the KX modifier are denied.

Along with the KX modifier thresholds, section 50202 also adds section 1833(g)(7)(B) of the Act that retains the targeted medical review (MR) process (first established through section 202 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)), but at a lower threshold amount of \$3,000. For CY 2018 (and each successive calendar year until 2028, at which time it is indexed annually by the MEI), the MR threshold is \$3,000 for PT and SLP services and \$3,000 for OT services. The targeted MR process means that not all claims exceeding the MR threshold amount are subject to review as they once were.

Section 1833(g)(8) of the Act, as redesignated by section 50202 of the BBA of 2018, retains the provider liability procedures which first became effective January 1, 2013, extending limitation of liability protections to beneficiaries who receive outpatient therapy services, when services are denied for certain reasons, including failure to include a necessary KX modifier.

2. Proposed Payment for Outpatient PT and OT Services Furnished by Therapy Assistants

Section 53107 of the Bipartisan Budget Act of 2018 (BBA of 2018) amended the Act to add a new subsection 1834(v) that addresses payment for outpatient therapy services for which payment is made under section 1848 or section 1834(k) of the Act that are furnished on or after January 1, 2022, in whole or in part by a therapy assistant (as defined by the Secretary). The new section 1834(v)(1) of the Act provides for payment of those services at 85 percent of the otherwise applicable Part B payment amount for the service. In accordance with section 1834(v)(1) of the Act, the reduced payment amount for such outpatient

therapy services is applicable when payment is made directly under the PFS as specified in section 1848 of the Act, for example when payment is made to therapists in private practice (TPPs); and when payment is made based on the PFS as specified in section 1834(k)(3) of the Act, for example, when payment is made for outpatient therapy services identified in sections 1833(a)(8) and (9) of the Act, including payment to providers that submit institutional claims for therapy services such as outpatient hospitals, rehabilitation agencies, skilled nursing facilities, home health agencies and comprehensive outpatient rehabilitation facilities (CORFs). The reduced payment rate under section 1834(v)(1) of the Act for outpatient therapy services when furnished in whole or in part by a therapy assistant is not applicable to outpatient therapy services furnished by critical access hospitals for which payment is made as specified in section 1834(g) of the Act.

To implement this payment reduction, section 1834(v)(2)(A) of the Act requires us to establish a new modifier, in a form and manner specified by the Secretary, by January 1, 2019 to indicate, in the case of an outpatient therapy service furnished in whole or in part by a therapy assistant, that the service was furnished by a therapy assistant. Although we generally consider all genres of outpatient therapy services together (PT/OT/SLP), we do not believe there are “therapy assistants” in the case of SLP services, so we propose to apply the new modifier only to services furnished in whole or in part by a physical therapist assistant (PTA) or an occupational therapist assistant (OTA). Section 1834(v)(2)(B) of the Act requires that each request for payment or bill submitted for an outpatient PT or OT service furnished in whole or in part by a therapy assistant on or after January 1, 2020, must include the established modifier. As such, the modifier will be required to be reported on claims for outpatient PT and OT services with dates of service on and after January 1, 2020, when the service is furnished in whole or in part by a therapy assistant, regardless of whether the reduced payment under section 1834(v)(1) of the Act is applicable. However, the required payment reductions do not apply for these services until January 1, 2022, as required by section 1834(v)(1) of the Act.

To implement this provision, we are proposing to establish two new modifiers to separately identify PT and OT services that are furnished in whole or in part by PTAs and OTAs,

respectively. We are proposing to establish two modifiers because the incurred expenses for PT and OT services are tracked and accrued separately in order to apply the two different KX modifier threshold amounts as specified by section 1833(g)(2) of the Act; and the use of the two proposed modifiers will facilitate appropriate tracking and accrual of services furnished in whole or in part by PTAs and OTAs. We additionally propose that these two therapy modifiers would be added to the existing three therapy modifiers—GP, GO, and GN—that are currently used to identify all therapy services delivered under a PT, OT or SLP plan of care, respectively. The GP, GO, and GN modifiers have existed since 1998 to track outpatient therapy services that were subject to the therapy caps. Although the therapy caps were repealed through amendments made to section 1833(g) of the Act by section 50202 of the BBA of 2018, as discussed in the above section, the statute continues to require that we track and accrue incurred expenses for all PT, OT, and SLP services, including those above the specified per beneficiary amounts for medically necessary therapy services for each calendar year; one amount for PT and SLP services combined, and another for OT services.

For purposes of implementing section 1834(v) of the Act through rulemaking as required under section 1834(v)(2)(C) of the Act, we are proposing to define “therapy assistant” as an individual who meets the personnel qualifications set forth at § 484.4 of our regulations for a physical therapist assistant and an occupational therapy assistant (PTA and OTA, respectively). We are proposing that the two new therapy modifiers would be used to identify services furnished in whole or in part by a PTA or an OTA; and, that these new therapy modifiers would be used instead of the GP and GO modifiers that are currently used to report PT and OT services delivered under the respective plan of care whenever the service is furnished in whole or in part by a PTA or OTA.

Effective for dates of service on and after January 1, 2020, the new therapy modifiers that identify services furnished in whole or in part by a PTA or OTA would be required to be used on all therapy claims instead of the existing modifiers GP and GO, respectively. As a result, in order to implement the provisions of the new subsection 1834(v) of the Act and carry out the continuing provisions of section 1833(g) of the Act as amended, we are proposing that, beginning in CY 2020, five therapy modifiers be used to track outpatient

therapy services instead of the current three. These five therapy modifiers include two new therapy modifiers to identify PT and OT services furnished by PTAs and OTAs, respectively, and three existing therapy modifiers—GP, GO and GN—that will be used when PT, OT, and SLP services, respectively, are fully furnished by therapists or when fully furnished by or incident to physicians and NPPs.

The creation of therapy modifiers specific to PT or OT services delivered under a plan of care furnished in whole or in part by a PTA or OTA would necessitate that we make changes to the descriptors of the existing GP and GO modifiers to clarify which qualified professionals, for example, therapist, physician, or NPP, can furnish the PT and OT services identified by these modifiers, and to differentiate them from the therapy modifiers specific to the services of PTAs and OTAs. We also propose to revise the GN modifier descriptor to conform to the changes to the GP and GO modifiers by clarifying the qualified professionals that furnish SLP therapy services.

We are proposing to define the new therapy modifiers for services furnished in whole or in part by therapy assistants and to revise the existing therapy modifier descriptors as follows:

- *New—PT Assistant services modifier (to be used instead of the GP modifier currently reported when a PTA furnishes services in whole or in part):* Services furnished in whole or in part by a physical therapist assistant under an outpatient physical therapy plan of care;

- *New—OT Assistant services modifier (to be used instead of the GO modifier currently reported when an OTA furnishes services in whole or in part):* Services furnished in whole or in part by occupational therapy assistant under an outpatient occupational therapy plan of care;

We are proposing that the existing GP modifier “Services delivered under an outpatient physical therapy plan of care” be revised to read as follows:

- *Revised GP modifier:* Services fully furnished by a physical therapist or by or incident to the services of another qualified clinician—that is, physician, nurse practitioner, certified clinical nurse specialist, or physician assistant—under an outpatient physical therapy plan of care;

We are proposing that the existing GO modifier “Services delivered under an outpatient occupational therapy plan of care” be revised to read as follows:

- *Revised GO modifier:* Services fully furnished by an occupational therapist or by or incident to the services of

another qualified clinician—that is, physician, nurse practitioner, certified clinical nurse specialist, or physician assistant—under an outpatient occupational therapy plan of care; and

We are proposing that the existing GN modifier that currently reads “Services delivered under an outpatient speech-language pathology plan of care” be revised to be consistent with the revisions to the GP and GO modifiers to read as follows:

- *Revised GN modifier:* Services fully furnished by a speech-language pathologist or by or incident to the services of another qualified clinician—that is, physician, nurse practitioner, certified clinical nurse specialist, or physician assistant—under an outpatient speech-language pathology plan of care.

As finalized in CY 2005 PFS final rule with comment (69 FR 66351 through 66354), and as required as a condition of payment under our regulations at §§ 410.59(a)(3)(iii), 410.60(a)(3)(iii), and 410.62(a)(3)(iii), the person furnishing outpatient therapy services incident to the physician, PA, NP or CNS service must meet the therapist personnel qualification and standards at § 484.4, except for licensure per section 1862(a)(20) of the Act. As such, we note that only a therapist, not a therapy assistant, can furnish outpatient therapy services incident to the services of a physician or a non-physician practitioner (NPP), so the new PT- and OT-Assistant therapy modifiers cannot be used on the line of service when the rendering practitioner identified on the claim is a physician or an NPP. For therapy services billed by physicians or NPPs, whether furnished personally or incident to their professional services, the GP or GO modifier is required for those PT or OT services furnished under an outpatient therapy plan.

We propose that all services that are furnished “in whole or in part” by a PTA or OTA are subject to the use of the new therapy modifiers. A new therapy modifier would be required to be used whenever a PTA or OTA furnishes all or part of any covered outpatient therapy service. However, we do not believe the provisions of section 1834(v) of the Act were intended to apply when a PTA or OTA performs portions of the service such as administrative tasks that are not related to their qualifications as a PTA or OTA. Rather, we believe the provisions of section 1834(v) were meant to apply when a PTA or OTA is involved in providing some or all of the therapeutic portions of an outpatient therapy service. We are proposing to define “in part,” for purposes of the proposed new modifiers, to mean any

minute of the outpatient therapy service that is therapeutic in nature, and that is provided by the PTA or OTA when acting as an extension of the therapist. Therefore, a service furnished “in part” by a therapy assistant would not include a service for which the PTA or OTA furnished only non-therapeutic services that others without the PTA’s or OTA’s training can do, such as scheduling the next appointment, greeting and gowning the patient, preparing or cleaning the room. We remind therapists and therapy providers that we do not recognize PTAs and OTAs to wholly furnish PT and OT evaluations and re-evaluations, that is, CPT codes 97161 through 97164 for PT and CPT codes 97165 through 97168 for OT; but to the extent that they do furnish part of an evaluative service, the appropriate therapy modifier must be used on the claim to signal that the service was furnished in part by the PTA or OTA, and the payment reduction should be applied once it goes into effect. We continue to believe that the clinical judgment and decision making involved in furnishing an evaluation or re-evaluation is similar to that involved with establishing the therapy plan that can only be established by a therapist, physician, or NPP (NP, CNS, or PA) as specified in § 410.61 of our regulations. In addition, PTAs and OTAs are not recognized separately in the statute to enroll as practitioners for purposes of independently billing for their services under the Medicare program. For these reasons, Pub. 100–02, Medicare Benefits Policy Manual, Chapter 15, sections 230.1 and 230.2 state that PTAs and OTAs “. . . may not provide evaluative or assessment services, make clinical judgments or decisions; develop, manage, or furnish skilled maintenance program services; or take responsibility for the service.” While we expect that the therapist will continue to furnish the majority of an evaluative procedure service, section 1834(v)(1) of the Act requires that the adjusted payment amount (85 percent of the otherwise applicable Part B payment amount) be applied when a therapy assistant furnishes a therapy service “in part,” including part of an evaluative service.

Additionally, we would like to clarify that the requirements for evaluations, including those for documentation, are separate and distinct from those for plans of care (plans). The plan is a statutory requirement under section 1861(p) of the Act for outpatient PT services (and through sections 1861(g) and 1861(l)(2) of the Act for outpatient OT and SLP services, respectively) and may only be established by a therapist

or physician. Through § 410.61(b)(5), NPs, CNSs, and PAs are also permitted to establish the plan. This means that if the evaluative procedure is furnished in part by an assistant, the new therapy modifiers that distinguish services furnished by PTAs or OTAs must be applied to the claim; however, the plan, which is not separately reported or paid, must be established by the supervising therapist who furnished part of the evaluation services as specified at § 410.61(b). When an evaluative therapy service is billed by a physician or an NPP as the rendering provider, either the physician/NPP or the therapist furnishing the service incident to the services of the physician or NPP, may establish the therapy plan in accordance with § 410.61(b). All regulatory and subregulatory plan requirements continue to apply.

To implement the new statutory provision at section 1834(v)(2)(A) of the Act, we are proposing to establish two new therapy modifiers to identify the services furnished in whole or in part by PTAs and OTAs. As required under section 1834(v)(2)(B) of the Act, claims from all providers of PT and OT services furnished on and after January 1, 2020, will be required to include these new PT- and OT-Assistant therapy modifiers for services furnished in whole or in part by a PTA or OTA. We propose that these modifiers will be required, when applicable, in place of the GP and GO modifiers currently used to identify PT and OT services furnished under an outpatient plan of care. To test our systems ahead of the required implementation date of January 1, 2020, we anticipate allowing voluntary reporting of the new modifiers at some point during CY 2019, which we will announce to our contractors and therapy providers through a Change Request, as part of our usual change management process.

We seek comments on these proposals.

3. Proposed Functional Reporting Modifications

Since January 1, 2013, all providers of outpatient therapy services, including PT, OT, and SLP services, have been required to include functional status information on claims for therapy services. In response to the Request for Information (RFI) on CMS Flexibilities and Efficiencies that was issued in the CY 2018 PFS proposed rule (82 FR 34172 through 34173), we received comments requesting burden reduction related to the reporting of the functional reporting requirements that were adopted to implement the requirements of section 3005(g) of the Middle Class

Tax Relief and Jobs Creation Act (MCTRJCA) of 2012, effective January 1, 2013.

After considering comments received through the CY 2013 PFS final rule with comment period (77 FR 68598–68978), we finalized the design of the functional reporting system. The MCTRJCA required us to implement a claims-based data collection strategy in order to collect data on patient function over the course of PT, OT, and SLP services in order to better understand patient condition and outcomes. The functional reporting system we implemented collects data using non-payable HCPCS G-codes (HCPCS codes G8978 through G8999 and G9158 through G9186) and modifiers (in the range CH through CN) to describe a patient’s functional limitation and severity at: (a) The time of the initial service, (b) at periodic intervals in sync with existing progress reporting intervals, (c) at discharge, and (d) when reporting certain evaluative and re-evaluative procedures (often times billed at time of initial service). Claims without the required functional reporting information are returned to therapy services providers, rather than denied, so that they can add the required information and resubmit claims. Therapy services providers must also document functional reporting information in the patient’s medical record each time it is reported. The MCTRJCA also specified that data from the functional reporting system were to be used to aid us in recommending changes to, and reforming Medicare payment for outpatient therapy services that were then subject to the therapy caps under section 1833(g) of the Act. We conducted an analysis that focused on the functional reporting data that have been submitted through the claims-based system, both by therapy discipline and by episodes of care by discipline using a similar episode definition (for example, clean 60 calendar day period) that was used in our prior utilization reports for CY 2008 through CY 2010 that can be found on the Therapy Services web page in the Studies and Reports page at <https://www.cms.gov/Medicare/Billing/TherapyServices/Studies-and-Reports.html>). However, we did not find the results compelling enough to use as a basis to recommend or undertake administrative reforms of the current payment mechanism for therapy services. Furthermore, going forward, the functional reporting data we would collect may be even less useful for purposes of recommending or reforming payment for therapy services because, as described earlier, section 50202 of the

Bipartisan Budget Act of 2018 (BBA of 2018) amended section 1833(g) of the Act to repeal the application of the Medicare outpatient therapy caps and associated exceptions process, while imposing protections to ensure therapy services are furnished when appropriate.

The general consensus of the commenters (organizations of physical therapists, occupational therapists, and speech-language pathologists, as well as other organizations of providers of therapy services and individual stakeholders) who responded to our RFI on burden reduction was that the functional reporting requirements for outpatient therapy services are overly complex and burdensome. The majority of commenters urged us to substantially revise and repurpose our functional reporting requirements for other programmatic purposes or to eliminate the functional reporting requirements all together. Most commenters to the RFI on burden reduction criticized us for not having shared with them an analysis of the functional reporting data we had collected to date, even though MCTRJCA does not require that we share any such analysis. A couple of commenters recommended we evolve our functional reporting requirements, at least in the short-term, with the following three changes: (a) Require reporting only at intake and discharge; (b) permit reporting through clinical data registries, electronic health records (EHRs), facility-based submission vehicles, etc., instead of the claims-based reporting required by section 3005(g) of MCTRJCA; and (c) allow functional reporting by therapy providers under MIPS as a clinical practice improvement activity. The short-term recommendation for reduced reporting was based on an independent analysis by one specialty society using a sample of our CY 2014 claims. That analysis noted that over an episode of care: (a) 93 percent reported when an evaluation code was reported; (b) 12 percent to 16 percent reported at the time of progress reporting interval; and (c) 36 percent of the episodes reported discharge data. In the long-term, these same RFI commenters believe our functional reporting system should be eliminated in favor of CMS policies that move therapy providers toward reporting using standardized measures of function. Other commenters suggested that we use standardized measures that reflect global function, or that are condition-specific. Some commenters would like to see CMS develop setting-appropriate quality measures for outpatient therapy that can

be used to both (a) measure functionality and (b) meld patient assessment data and functional measures with relevant measures developed in response to the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act of 2014) (Pub. L. 113–185) that is applicable to CMS post-acute care (PAC) settings.

As part of the requirements of section 3005(g) of MCTRJCA, we established our functional reporting claims-based data collection strategy effective January 1, 2013 in the CY 2013 PFS final rule (77 FR 689580 through 68978) and will have been collecting these functional reporting data for the last 5 years at the close of CY 2018. Because the data from the functional reporting system were to be used to inform our recommendations and reform of Medicare payment for outpatient therapy services that are subject to the therapy caps under section 1833(g) of the Act, we reviewed and analyzed the data internally but did not find them particularly useful in considering how to reform payment for therapy services as an alternative to the therapy caps. In the meantime, section 50202 of BBA of 2018, as discussed previously, amended section 1833(g) of the Act to reform therapy payment. Because section 3005(g) of MCTRJCA was not codified into the Act, and did not specify how long the data collection strategy should last, we do not believe it was intended to last indefinitely. We note that we share commenters' concerns, including those who favor the elimination of functional reporting because it is overly complex and burdensome to report, and that those that questioned the utility of the collected data given the lack of standardized measures used to report the severity of the functional limitation being reported. In response to commenters' concerns that we have not yet shared an analysis of the collected functional reporting data with them, we note that we have not published or shared the results to date because we did not find the results informative when reviewing them for purpose of the section 3005(g) of MCTRJCA requirement. A few commenters requested that we continue to collect functional reporting data in a reduced format—at the outset and at discharge of the therapy episode—as a collective short-term solution, while favoring the elimination of functional reporting in the long-term because, according to our data and the commenters' own data, the discharge data are only infrequently reported. However, we do not believe that collecting additional years of

functional reporting data in this reduced format would add utility to our data collection efforts. After consideration of these comments on the RFI along with a review of all of the requirements under section 3005(g) of MCTRJCA, and in light of the recent statutory amendments to section 1833(g) of the Act, we have concluded that continuing to collect more years of these functional reporting data, whether through the same or a reduced format, will not yield additional information that would be useful to inform future analyses, and that allowing the current functional reporting requirements to remain in place could result in unnecessary burden for providers of therapy services without providing further benefit to the Medicare program in the form of additional data.

As a result, we are proposing to discontinue the functional reporting requirements for services furnished on or after January 1, 2019. Specifically, we are proposing to amend our regulations by removing the following: (1) Conditions of payment at §§ 410.59(a)(4), 410.60(a)(4), 410.62(a)(4), and 410.105(d) that require claims for OT, PT, SLP, and Comprehensive Outpatient Rehabilitation Facility (CORF) PT, OT, and SLP services, respectively, to contain prescribed information on patient functional limitations; and, (2) the functional reporting-related phrase that requires the plan's goals to be consistent with functional information on the claim at § 410.61(c) for outpatient PT, OT, and SLP services and at § 410.105(c)(1)(ii) for the PT, OT, and SLP services in CORFs. In addition, we would: (1) Remove the functional reporting subregulatory requirements implemented primarily through Change Request 8005 last issued on December 21, 2012, via Transmittal 2622; (2) eliminate the functional reporting standard systems edits we have applied to claims; and (3) remove the functional reporting requirement provisions in our internet Only Manual (IOM) provisions including the Medicare Claims Processing Manual, Chapter 5; and, the functional reporting requirements in Chapters 12 and 15 of the Medicare Benefits Policy Manual.

If finalized, our proposal would end the requirements for the reporting and documentation of functional limitation G-codes (HCPCS codes G8978 through G8999 and G9158 through G9186) and severity modifiers (in the range CH through CN) for outpatient therapy claims with dates of service on and after January 1, 2019. Accordingly, with the conclusion of our functional reporting system for dates of service after

December 31, 2018, we would delete the applicable non-payable HCPCS G-codes specifically developed to implement that system through the CY 2013 PFS final rule with comment period (77 FR 68598 through 68978).

We are seeking comment on these proposals.

N. Part B Drugs: Application of an Add-On Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments

Consistent with statutory provisions in section 1847A of the Act, many current Medicare Fee For Service (FFS) payments for separately payable drugs and biologicals furnished by providers and suppliers include an add-on set at 6 percent of the volume-weighted average sales price (ASP) or wholesale acquisition cost (WAC) for the drug or biological (the “6 percent add-on”). Although section 1847A of the Act does not specifically state what the 6 percent add-on represents, it is widely believed to include services associated with drug acquisition that are not separately paid for, such as handling, and storage, as well as additional mark-ups in drug distribution channels. The 6 percent add-on described in section 1847A of the Act has raised concerns because more revenue can be generated from percentage-based add-on payments for expensive drugs, and an opportunity to generate more revenue may create an incentive for the use of more expensive drugs (MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2015, <http://medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf>, pages 65 through 72). Also, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) March 8, 2016, Issue Briefing pointed out that that administrative complexity and overhead costs are not exactly proportional to the price of a drug (<https://aspe.hhs.gov/pdf-report/medicare-part-b-drugs-pricing-and-incentives>). Thus, the suitability of using a percentage of the volume-weighted average sales price or WAC of the drug or biological for an add-on payment may vary depending on the price of the drug or how the payment rate has been determined.

While the add-on percentage for drug payments made under section 1847A of the Act is typically applied to the ASP, the same 6 percent add-on is also applied to the WAC to determine the Part B drug payment allowances in the following situations. First, for single source drugs as authorized in section 1847A(b)(4) of the Act, payment is made using the lesser of ASP or WAC; and

section 1847A(b)(1) of the Act requires that a 6 percent add-on be applied regardless of whether WAC or ASP is less. Second, for drugs and biologicals where average sales price during first quarter of sales is unavailable, section 1847A(c)(4) of the Act allows the Secretary to determine the payment amount for the drug or biological based on the WAC or payment methodologies in effect on November 1, 2003. We note that this provision does not specify that an add-on percentage be applied if WAC-based payment is used, nor is an add-on percentage specified in the implementing regulations at § 414.904(e)(4). The application of the add-on percentage to WAC-based payments during a period where partial quarter ASP data was available was discussed in the 2011 PFS final rule with comment (75 FR 73465 through 73466). Third, in situations where Medicare Administrative Contractors (MACs) determine pricing for drugs that do not appear on the ASP pricing files and for new drugs, WAC-based payment amounts may also be used, as discussed in Chapter 17, Section 20.1.3 of the Medicare Claims Processing Manual. This section of the Manual describes the use of a 6 percent add-on.

The incorporation of discounts in the determination of payment amounts made for Part B drug varies. Most Part B drug payments are based on the drug's or biological's ASP; as provided in section 1847A(c)(3) of the Act, the ASP is net of many discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase, chargebacks, rebates (other than rebates under Medicaid drug rebate program), etc. In contrast, the WAC of a drug or biological is defined in section 1847A(c)(6)(B) of the Act as the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. Because the WAC does not include discounts, it typically exceeds ASP, and the use of a WAC-based payment amount for the same drug results in higher dollar payments than the use of an ASP-based payment amount.

Although discussions about the add-on tend to focus on ASP-based payments (because ASP-based payments are more common than WAC-based payments), the add-on for WAC-based payments has also been raised in the June 2017 MedPAC Report to the

Congress (http://www.medpac.gov/docs/default-source/reports/jun17-report-to-congress_sec.pdf, pages 42 through 44). The MedPAC report focused on how the 2 quarter lag in payments determined under section 1847A of the Act led to a situation where undiscounted WAC-based payment amounts determined using information from 2 quarters earlier were used to pay for drugs that providers purchased at a discount. To determine the extent of the discounts, MedPAC sampled new, high-expenditure Part B drugs and found that these drugs' ASPs were generally lower than their WACs. Seven out of the 8 drugs showed pricing declines from initial WAC to ASP one year after being listed in the ASP pricing files with the remaining product showing no change, which suggests purchasers received discounts that WAC did not reflect. MedPAC further cited a 2014 OIG report (OIG, *Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs*, (OEI-12-13-00040), July 2014) to illustrate that there may be differences between WAC and ASP in other instances in which CMS utilizes WAC instead of ASP and noted that OIG found that “WACs often do not reflect actual market prices for drugs.” MedPAC also characterized Part B payments based on undiscounted list prices for products that were available at a discount as excessive. The report suggested that greater parity between ASP-based acquisition costs and WAC-based payments for Part B drugs could be achieved and recommended changing the 6 percent add-on for WAC-based payments to 3 percent. A 3 percent change was recommended based on statements made by industry, MedPAC's analysis of new drug pricing, and OIG data. The report also mentioned that discounts on WAC, such as prompt pay discounts, were available soon after the drug went on the market.

In the case of a drug or biological during an initial sales period in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. In other words, although payments under this section may be based on WAC, unlike section 1847A(b) of the Act (which specifies that certain payments must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to partial quarter WAC-based pricing. Consistent with section 1847A(c)(4) of the Act, we are proposing that effective January 1,

2019, WAC based payments for Part B drugs made under section 1847A(c)(4) of the Act, utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used. We are proposing a 3 percent add-on because this percentage is consistent with MedPAC's analysis and recommendations discussed in the paragraph above and cited in their June 2017 Report to the Congress. Although other approaches for modifying the add-on amount, such as a flat fee, or percentages that vary with the cost of a drug, are possible, we are proposing a fixed percentage in order to be consistent with other provisions in section 1847A of the Act which specify fixed add-on percentages of 6 percent (1847A(b)) or 3 percent (section 1847A(d)(3)(C) of the Act). A fixed percentage is also administratively simple to implement and administer, is predictable, and is easy for manufacturers, providers and the public to understand.

We have also reviewed corresponding regulation text at § 414.904(e)(4). To conform the regulation text more closely to the statutory language at section 1847A(c)(4) of the Act, we are also proposing to strike the word "applicable" from paragraph (e)(4). Section 1847A(c)(4) of the Act does not use the term "applicable" to describe the payment methodologies in effect on November 1, 2003.

If we were to finalize these proposals, we would also change the policy articulated in the Claims Processing Manual that describes the application of the 6 percent add-on to payment determinations made by MACs for new drugs and biologicals. Chapter 17 section 20.1.3 of the Claims Processing Manual (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>) states that WAC-based payment limits for drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the Food and Drug Administration, and that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, are based on 106 percent of WAC. Invoice-based pricing is used if the WAC is not published. In OPPS, the payment allowance limit is 95 percent of the published Average Wholesale Price (AWP). We would change our policy to permit MACs to use an add-on percentage of up to 3 percent for WAC-based payments for new drugs. MACs have longstanding authority to make payment determinations when we do not publish a payment limit in our national Part B drug pricing files and

when new a drug becomes available. This proposal would preserve consistency with our proposed national pricing policy and would apply when MACs perform pricing determinations, for example during the period when ASPs have not been reported. This proposed policy would not alter OPPS payment limits.

We note that these proposals do not include WAC-based payments for single source drugs under section 1847A(b) of the Act, that is, where the statute specifies that the payment limit is 106 percent of the lesser of ASP or WAC.

We have stated in previous rulemaking that it is desirable to have fair reimbursement in a healthy marketplace that encourages product development (80 FR 71101). We have also stated that we seek to promote innovation to provide more options to patients and physicians, and competition to drive prices down (82 FR 53183). These positions have not changed. However, since 2011, concern about the impact of drug pricing and spending on Part B drugs has continued to grow. From 2011 to 2016, Medicare Part B drug spending increased from \$17.6 billion to \$28.0 billion, representing a compound annual growth rate of 9.8 percent, with per capita spending increasing 54 percent, from \$532 to \$818 (Based on Spending and Enrollment Data from Centers for Medicare and Medicaid Services Office of Enterprise Data and Analytics). These increases affect the spending by Medicare and beneficiary out-of-pocket costs. In the context of these concerns, we believe that implementation of these proposals will improve Medicare payment rates by better aligning payments with drug acquisition costs, especially for the growing number of drugs with high annual spending and high launch prices where single doses can cost tens or even hundreds of thousands of dollars. The proposals will also decrease beneficiary cost sharing. A 3 percentage point reduction in the total payment allowance will reduce a patient's 20 percent Medicare Part B copayment—for a drug that costs many thousands of dollars per dose, this can result in significant savings to an individual. The proposed approach would help Medicare beneficiaries afford to pay for new drugs by reducing out of pocket expenses and would help counteract the effects of increasing launch prices for newly approved drugs and biologicals. Finally, the proposals are consistent with recent MedPAC recommendations.

III. Other Provisions of the Proposed Rule

A. Clinical Laboratory Fee Schedule

1. Background

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS) under sections 1832, 1833(a), (b) and (h), and 1861 of the Social Security Act (the Act). Under the previous methodology, CDLTs were paid based on the lesser of: (1) The amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI-U), and reduced by a multi-factor productivity adjustment and other statutory adjustments, but were not otherwise updated or changed.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. The CLFS final rule, entitled Medicare Clinical Diagnostic Laboratory Tests Payment System (CLFS final rule), published in the **Federal Register** on June 23, 2016, implemented section 1834A of the Act. Under the CLFS final rule, "reporting entities" must report to CMS during a "data reporting period" "applicable information" collected during a "data collection period" for their component "applicable laboratories." Applicable information is defined at § 414.402 as, with respect to each CDLT for a data collection period: Each private payor rate for which final payment has been made during the data collection period; the associated volume of tests performed corresponding to each private payor rate; and the specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test. Applicable information does not include information about a test for which payment is made on a capitated basis. An applicable laboratory is defined at § 414.502, in part, as an entity that is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA) definition at § 493.2) that bills Medicare Part B under its own National Provider Identifier

(NPI). In addition, an applicable laboratory is an entity that receives more than 50 percent of its Medicare revenues during a data collection period from the CLFS and/or the Physician Fee Schedule (PFS). We refer to this component of the applicable laboratory definition as the “majority of Medicare revenues threshold.” The definition of applicable laboratory also includes a “low expenditure threshold” component which requires an entity to receive at least \$12,500 of its Medicare revenues from the CLFS for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs).

The first data collection period, for which applicable information was collected, occurred from January 1, 2016 through June 30, 2016. The first data reporting period, during which reporting entities reported applicable information to CMS, occurred January 1, 2017 through March 31, 2017. On March 30, 2017, we announced a 60-day enforcement discretion period of the assessment of Civil Monetary Penalties (CMPs) for reporting entities that failed to report applicable information. Additional information about the 60-day enforcement discretion period may be found on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf>.

In general, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to us during the data reporting period, and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new ADLT or new CDLT) can be reduced as compared to the payment rates for the preceding year. For the first 3 years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. For most CDLTs, the data collection period, data reporting

period, and payment rate update occur every 3 years. As such, the next data collection period for most CDLTs will be January 1, 2019 through June 30, 2019, and the next data reporting period will be January 1, 2020 through March 31, 2020, with the next update to CLFS occurring on January 1, 2021. Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule (81 FR 41036 through 41101).

2. Recent Stakeholder Feedback

After the initial data collection and data reporting periods, we received stakeholder feedback on a range of topics related to the private payor rate-based CLFS. Some stakeholders expressed concern that the CY 2018 CLFS payments rates are based on applicable information from only a relatively small number of laboratories. Some stakeholders stated that, because most hospital-based laboratories were not applicable laboratories, and therefore, did not report applicable information during the initial data reporting period, the CY 2018 CLFS payment rates do not reflect their information and are inaccurate. Other stakeholders were concerned that the low expenditure threshold excluded most physician office laboratories and many small independent laboratories from reporting applicable information.

In determining payment rates under the private payor rate-based CLFS, one of our objectives is to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts, for example, from independent laboratories, hospital outreach laboratories, and physician office laboratories, without imposing undue burden on those entities. As we noted throughout the CLFS final rule, we believe it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT, and minimizing the reporting burden for entities. In response to stakeholder feedback and in the interest of facilitating our goal, we are proposing one change, discussed below, to the Medicare CLFS for CY 2019. We believe this proposal may result in more data being used on which to base CLFS payment rates.

In addition to this proposal, we are soliciting public comments on other approaches that have been requested by some stakeholders who suggested that such approaches would result in CMS receiving even more applicable information to use in establishing CLFS

payment rates. The approaches include revising the definition of applicable laboratory and changing the low expenditure threshold. These topics are discussed below.

3. Proposed Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory

In order for a laboratory to meet the majority of Medicare revenues threshold, section 1834A(a)(2) of the Act requires that, “with respect to its revenues under this title, a majority of such revenues are from” the CLFS and the PFS in a data collection period. In the CLFS final rule, we stated that “revenues under this title” are payments received from the Medicare program, which includes fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage (MA) payments under Medicare Part C, and prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period (81 FR 41043). This total Medicare revenues amount (the denominator in the majority of Medicare revenues threshold calculation) is compared to the total of Medicare revenues received from the CLFS and/or PFS (the numerator in the majority of Medicare revenues threshold calculation). If the numerator is greater than 50 percent of the denominator for a data collection period, the entity has met the majority of Medicare revenues threshold criterion. We reflected that requirement in § 414.502 in the third paragraph of the definition of applicable laboratory.

We have considered that our current interpretation of total Medicare revenues may have the effect of excluding laboratories that furnish Medicare services to a significant number of beneficiaries enrolled in MA plans under Medicare Part C from meeting the majority of Medicare revenues threshold criterion, and therefore, from qualifying as applicable laboratories. For instance, if a laboratory has a significant enough Part C component so that it is receiving greater than 50 percent of its total Medicare revenues from MA payments under Part C, it would not meet the majority of Medicare revenues threshold because its revenues derived from the CLFS and/or PFS would not constitute a majority of its total Medicare revenues. We believe that if we were to exclude MA plan revenues from total Medicare revenues, more laboratories of all types may meet the majority of Medicare revenues threshold, and therefore, the definition

of applicable laboratory, because it would have the effect of decreasing the amount of total Medicare revenues and increase the likelihood that a laboratory's CLFS and PFS revenues would constitute a majority of its Medicare revenues.

We believe section 1834A of the Act permits an interpretation that MA plan payments to laboratories not be included in the total Medicare revenues component of the majority of Medicare revenues threshold calculation. Rather, MA plan payments to laboratories can be considered to only be private payor payments under the CLFS. We emphasize here that this characterization of MA plan payments is limited to only the CLFS for purposes of defining applicable laboratory. Whether MA plan payments to laboratories or other entities are considered Medicare "revenues" or "private payor payments" in other contexts in the Medicare program is irrelevant here. Nor does our characterization of MA plan payments as private payor payments for purposes of the CLFS have any bearing on any aspect of the Medicare program other than the CLFS. This is because of language included in section 1834A of the Act that is specifically targeted to the CLFS, explained below.

As noted above, we defined total Medicare revenues for purposes of the majority of Medicare revenues threshold calculation to include fee-for-service payments under Medicare Parts A and B, as well as MA payments under Medicare Part C, and prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period. However, section 1834A(a)(8) of the Act, which defines the term "private payor," identifies at section 1834A(a)(8)(B) a "Medicare Advantage plan under Part C" as a type of private payor. Under the private payor rate-based CLFS, CLFS payment amounts are based on private payor rates that are reported to CMS. So, an applicable laboratory that receives Medicare Advantage (MA) plan payments is to consider those MA plan payments in identifying its applicable information, which must be reported to

CMS. We believe it is more logical to not consider MA plan payments under Part C to be both Medicare revenues for determining applicable laboratory status and private payor rates for purposes of reporting applicable information. Congress contemplated that applicable laboratories would furnish MA services, as reflected in the requirement that private payor rates must be reported for MA services. However, under our current definition of applicable laboratory, laboratories that furnish MA services, particularly those that furnish a significant amount, are less likely to meet the majority of Medicare revenues threshold, which means they would be less likely to qualify as applicable laboratories, and therefore, to report private payor rates for MA services.

Therefore, after further review and consideration of the new private payor rate-based CLFS, we believe it is appropriate to include MA plan revenues as only private payor payments rather than both Medicare revenues, for the purpose of determining applicable laboratory status, and private payor payments, for the purpose of specifying what is applicable information. Such a change would have the effect of eliminating the laboratory revenue generated from a laboratory's Part C-enrolled patient population as a factor in determining whether a majority of the laboratory's Medicare revenues are comprised of services paid under the CLFS or PFS. We believe this change would permit a laboratory with a significant Medicare Part C revenue component to be more likely to meet the majority of Medicare revenues threshold and qualify as an applicable laboratory. In other words, MA payments are currently included as total Medicare revenues (the denominator). In order to meet the majority of Medicare revenues threshold, the statute requires a laboratory to receive the majority of its Medicare revenues from the CLFS and or PFS. If MA plan payments were excluded from the total Medicare revenues calculation, the denominator amount would decrease. If the denominator amount decreases, the likelihood increases that a laboratory would qualify as an applicable

laboratory. Therefore, we believe this proposal responds directly to stakeholders' concerns regarding the number of laboratories for which applicable information must be reported because a broader representation of the laboratory industry may qualify as applicable laboratories, which means we would receive more applicable information to use in setting CLFS payment rates.

For these reasons, we are proposing that MA plan payments under Part C would not be considered Medicare revenues for purposes of the applicable laboratory definition. We would revise paragraph (3) of the definition of applicable laboratory at § 414.502 accordingly. We reiterate that not characterizing MA plan payments under Medicare Part C as Medicare revenues would be limited to the definition of applicable laboratory under the CLFS, and would not affect, reflect on, or otherwise have any bearing on any other aspect of the Medicare program.

In an effort to provide stakeholders a better understanding of the potential reporting burden that may result from this proposal, we are providing a summary of the distribution of data reporting that occurred for the first data reporting period. If we were to finalize the proposed change to the majority of Medicare revenues threshold component of the definition of applicable laboratory, additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C could potentially qualify as applicable laboratories, in which case their data would be reported to us. As discussed previously, we received over 4.9 million records from 1,942 applicable laboratories for the initial data reporting period, which we used to set CY 2018 CLFS rates. Additional analysis shows that the average number of records reported for an applicable laboratory was 2,573. The largest number of records reported for an applicable laboratory was 457,585 while the smallest amount was 1 record. A summary of the distribution of reported records from the first data collection period is illustrated in the Table 24.

TABLE 24—SUMMARY OF RECORDS REPORTED FOR FIRST DATA REPORTING PERIOD

[By applicable laboratory]

Total records	Average records	Min records	Max records	Percentile distribution of records				
				10th	25th	50th	75th	90th
4,995,877	2,573	1	457,585	23	79	294	1,345	4,884

Assuming a similar distribution of data reporting for the next data reporting period, the mid-point of reported records for an applicable laboratory would be approximately 300 (50th percentile for the first data reporting period was 294). However, as illustrated in Table 24, the number of records reported varies greatly, depending on the volume of services performed by a given laboratory. Laboratories with larger test volumes, for instance at the 90th percentile, should expect to report more records as compared to the midpoint used for this analysis. Likewise, laboratories with smaller test volume, for instance at the 10th percentile, should expect to report less records as compared to the midpoint.

We welcome comments on our proposal to modify the definition of applicable laboratory to exclude MA plan payments under Part C as Medicare revenues.

4. Solicitation of Public Comments on Other Approaches to Defining Applicable Laboratory

As noted previously, we define applicable laboratory at the NPI level, which means the laboratory's own billing NPI is used to identify a laboratory's revenues for purposes of determining whether it meets the majority of Medicare revenues threshold and the low expenditure threshold components of the applicable laboratory definition. For background purposes, the following summarizes some of the considerations we made in establishing this policy.

In the CLFS proposed rule, entitled Medicare Clinical Diagnostic Laboratory Tests Payment System, published in the October 1, 2015 **Federal Register**, we proposed to define applicable laboratory at the TIN level so that an applicable laboratory would be an entity that reports tax-related information to the IRS under a TIN with which all of the NPIs in the entity are associated, and was itself a laboratory or had at least one component that was a laboratory, as defined in § 493.2. In the CLFS proposed rule, we discussed that we considered proposing to define applicable laboratory at the NPI level. However, we did not propose that approach because we believed private payor rates for CDLTs are negotiated at the TIN level and not by individual laboratory locations at the NPI level. Numerous stakeholders had indicated that the TIN-level entity is the entity negotiating pricing, and therefore, is the entity in the best position to compile and report applicable information across its multiple NPIs when there are

multiple NPIs associated with a TIN-level entity. We stated that we believed defining applicable laboratory by TIN rather than NPI would result in the same applicable information being reported, and would require reporting by fewer entities, and therefore, would be less burdensome to applicable laboratories. In addition, we stated that we did not believe reporting at the TIN level would affect or diminish the quality of the applicable information reported. To the extent the information is accurately reported, we expected reporting at a higher organizational level to produce exactly the same applicable information as reporting at a lower level (80 FR 59391 through 59393).

Commenters who objected to our proposal to define applicable laboratory at the TIN level stated that our definition would exclude hospital laboratories because, in calculating the applicable laboratory's majority of Medicare revenues amount, which looks at the percentage of Medicare revenues from the PFS and CLFS across the entire TIN-level entity, virtually all hospital laboratories would not be considered an applicable laboratory. Many commenters expressed particular concern that our proposed definition would exclude hospital outreach laboratories, stating that hospital outreach laboratories, which do not provide laboratory services to hospital patients, are direct competitors of the broader independent laboratory market, and therefore, excluding them from the definition of applicable laboratory would result in incomplete and inappropriate applicable information, which would skew CLFS payment rates. Commenters maintained that CMS needed to ensure reporting by a broad scope of the laboratory market to meet what they viewed as Congressional intent that all sectors of the laboratory market be included to establish accurate market-based rates (81 FR 41045).

In issuing the CLFS final rule, we found particularly compelling the comments that urged us to adopt a policy that would better enable hospital outreach laboratories to be applicable laboratories because we agreed hospital outreach laboratories should be accounted for in the new CLFS payment rates. We noted that hospital outreach laboratories are laboratories that furnish laboratory tests for patients who are not admitted hospital inpatients or registered outpatients of the hospital and who are enrolled in Medicare separately from the hospital of which they are a part as independent laboratories that do not serve hospital patients. We believed it was important to facilitate reporting of private payor

rates for hospital outreach laboratories to ensure a broader representation of the national laboratory market to use in setting CLFS payment amounts (81 FR 41045).

We were clear in the CLFS final rule, however, that we believe Congressional intent was to effectively exclude hospital laboratories as applicable laboratories, which was apparent from the statutory language, in particular, the majority of Medicare revenues threshold criterion in section 1834A(a)(2) of the Act. Section 1834A(a)(2) of the Act provides that, to qualify as an applicable laboratory, an entity's revenues from the CLFS and the PFS needs to constitute a majority of its total Medicare payments received from the Medicare program for a data collection period. What we found significant was that most hospital laboratories would not meet that majority of Medicare revenues threshold because their revenues under the IPPS and OPFS alone would likely far exceed the revenues they received under the CLFS and PFS. Therefore, we believe the statute intended to limit reporting primarily to independent laboratories and physician offices (81 FR 41045 through 41047). For a more complete discussion of the definition of applicable laboratory, see the CLFS final rule (81 FR 41041 through 41051).

a. Stakeholder Continuing Comments and Stakeholder-Suggested Alternative Approaches

As noted above, in response to public comments, we finalized that an applicable laboratory is the NPI-level entity so that a hospital outreach laboratory assigned a unique NPI, separate from the hospital of which it is a part, is able to meet the definition of applicable laboratory and its applicable information can be used for CLFS rate-setting. We continue to believe that the NPI is the most effective mechanism for identifying Medicare revenues for purposes of determining applicable laboratory status and identifying private payor rates for purposes of reporting applicable information. Once a hospital outreach laboratory obtains its own unique billing NPI and bills for services using its own unique NPI, Medicare and private payor revenues are directly attributable to the hospital outreach laboratory. By defining applicable laboratory using the NPI, Medicare payments (for purposes of determining applicable laboratory status) and private payor rates and the associated volume of CDLTs can be more easily identified and reported to us. We also believe that, if finalized, our proposal to exclude MA plan revenues under Medicare Part C from total Medicare revenues in the

definition of applicable laboratory may increase the number of entities meeting the majority of Medicare revenues threshold, and therefore, qualifying for applicable laboratory status. In summary, we believe the proposed change to the total Medicare revenues component of the applicable laboratory definition and our current policy that requires an entity to bill Medicare Part B under its own NPI, may increase the number of hospital outreach laboratories qualifying as applicable laboratories.

In addition, we are confident that our current policy supports our collecting sufficient applicable information in the next data reporting period, and that we received sufficient and reliable applicable information with which we set CY 2018 CLFS rates, and that those rates are accurate. For instance, we received applicable information from laboratories in every state, the District of Columbia, and Puerto Rico. This data included private payor rates for almost 248 million laboratory tests conducted by 1,942 applicable laboratories, with over 4 million records of applicable information. In addition, as we've noted, the largest laboratories dominate the market, and therefore, most significantly affect the payment weights (81 FR 41049). Given that the largest laboratories reported their applicable information to CMS in the initial data reporting period, along with many smaller laboratories, we believe the data we used to calculate the CY 2018 CLFS rates was sufficient and resulted in accurate weighted medians of private payor rates.

However, we continue to consider refinements to our policies that could lead to including even more applicable information for the next data reporting period. To that end, the comments and alternative approaches suggested by stakeholders, even though some were first raised prior to the CLFS final rule, are presented and considered for comment now.

(1) Using Form CMS–1450 Bill Type 14x To Determine Majority of Medicare Revenues and Low Expenditure Thresholds

Some stakeholders that expressed concern over the CY 2018 CLFS payments rates stated that the NPI-based definition of applicable laboratory reduces the number of hospital outreach laboratories reporting data. These stakeholders suggested we revise the definition specifically for the purpose of including more hospital outreach laboratories. Under a suggested approach, a laboratory could determine whether it meets the majority of Medicare revenues threshold and low

expenditure threshold using only the revenues from services reported on the Form CMS–1450 (approved Office of Management and Budget number 0938–0997) 14x bill type, which is used only by hospital outreach laboratories. Therefore, per the stakeholder suggestions, we are seeking public comments on the following approach.

This approach would revise the definition of applicable laboratory to permit the revenues identified on the Form CMS–1450 14x bill type to be used instead of the revenues associated with the NPI the laboratory uses, to determine whether it meets the majority of Medicare revenues threshold (and the low expenditure threshold). Under this approach, the applicable revenues would be based on the bills used for hospital laboratory services provided to non-patients, which are paid under Medicare Part B (that is, the 14x bill type). If we pursued this approach, we would have to modify the definition of applicable laboratory in § 414.502 by indicating that an applicable laboratory may include an entity that bills Medicare Part B on the Form CMS–1450 14x bill type.

Although using the 14x bill type could alleviate some initial, albeit limited, administrative burden on hospital outreach laboratories to obtain a unique billing NPI, we would have operational and statutory authority concerns about defining applicable laboratory by the Form CMS–1450 14x bill type.

First, defining applicable laboratory using the Form CMS–1450 14x bill type does not identify an entity the way an NPI does. Whereas an NPI is associated with a provider or supplier to determine specific Medicare revenues, the 14x bill type is merely a billing mechanism that is currently used only for a limited set of services. Under an approach that permits laboratories to meet the majority of Medicare revenues threshold using the 14x bill type, private payor rates (and the volume of tests paid at those rates) would have to be identified that are associated with only the outreach laboratory services of a hospital's laboratory business. However, some private payors, such as MA plans, may not require hospital laboratories to use the 14x bill type for their outreach laboratory services. To the extent a private payor does not require hospital outreach laboratory services to be billed on a 14x bill type (which specifically identifies outreach services), hospitals may need to develop their own mechanism for identifying and reporting only the applicable information associated with its hospital outreach laboratory services. In light of this

possible scenario, we are interested in public comments about the utility of using the 14x bill type in the way we have described and on the level of administrative burden created if we defined applicable laboratory using the Form CMS–1450 14x bill type.

Second, we question whether hospitals would have sufficient time after publication of a new final rule that included using the Form CMS–1450 14x bill type, and any related subregulatory guidance, to develop and implement the information systems necessary to collect private payor rate data before the start of the next data collection period, that is, January 1, 2019. To that end, we are interested in public comments as to whether revising the definition of applicable laboratory to use the Form CMS–1450 14x bill type would allow laboratories sufficient time to make the necessary systems changes to identify applicable information before the start of the next data collection period.

Third, we believe defining applicable laboratory at the NPI level, as we currently do, provides flexibility for hospital outreach laboratories to not obtain a unique billing NPI, which may be significant particularly where a hospital outreach laboratory performs relatively few outreach services under Medicare Part B. For example, under the current definition of applicable laboratory, if a hospital outreach laboratory's CLFS revenues in a data collection period are typically much less than the low expenditure threshold, the hospital of which it is a part could choose not to obtain a separate NPI for its outreach laboratory and could thus avoid determining applicable laboratory status for its outreach laboratory component. In contrast, if laboratories were permitted to use the Form CMS–1450 14x bill type, revenues attributed to the hospital outreach laboratory would have to be calculated in every instance where those services exceeded the low expenditure threshold. This would be true even for a hospital outreach laboratory that performs relatively few outreach services under Medicare Part B. Therefore, we are interested in comments concerning this aspect of using the 14x bill type definition.

Fourth, and significantly, we believe that if we were to utilize such an approach in defining applicable laboratory, all hospital outreach laboratories would meet the majority of Medicare revenues threshold. At this time, we believe that this approach would be inconsistent with the statute. By virtue of the majority of Medicare revenues threshold, the statute defines applicable laboratory in such a way that

not all laboratories qualify as applicable laboratories. However, if we were to use the CMS-1450 14x bill type to define an applicable laboratory, all hospital outreach laboratories that use the 14x bill type would meet the majority of Medicare revenues threshold.

Accordingly, we are interested in public comments regarding whether this definition would indeed be inconsistent with the statute, as well as comments that can identify circumstances under this definition whereby a hospital outreach laboratory would not meet the majority of Medicare revenues threshold.

(2) Using CLIA Certificate To Define Applicable Laboratories

Some industry stakeholders have requested that we use the CLIA certificate rather than the NPI to identify a laboratory that would be considered an applicable laboratory. We discussed in the CLFS proposed rule (80 FR 59392) why not all entities that meet the CLIA regulatory definition at § 493.2 would be applicable laboratories, and therefore, we did not propose to use CLIA as the mechanism for defining applicable laboratory. However, some commenters to the CLFS proposed rule suggested we use the CLIA certificate to identify the organizational entity that would be considered an applicable laboratory so that each entity that had a CLIA certificate would be an applicable laboratory (81 FR 41045). We considered those comments in the CLFS final rule and discussed why we chose not to adopt that approach.

Among other reasons, we explained in the CLFS final rule that we believed a CLIA certificate-based definition of applicable laboratory would be overly inclusive by including all hospital laboratories, as opposed to just hospital outreach laboratories. In addition, the CLIA certificate is used to certify that a laboratory meets applicable health and safety regulations in order to furnish laboratory services. It is not associated with Medicare billing so, unlike for example, the NPI, with which revenues for specific services can easily be identified, the CLIA certificate cannot be used to identify revenues for specific services. We also indicated that we did not see how a hospital would determine whether its laboratories would meet the majority of Medicare revenues threshold (and the low expenditure threshold) using the CLIA certificate as the basis for defining an applicable laboratory. In addition, we stated that, given the difficulties many hospitals would likely have in determining whether their laboratories are applicable laboratories,

we also believed hospitals may object to using the CLIA certificate (81 FR 41045).

However, in light of stakeholders' suggestions to use the CLIA certificate to include hospital outreach laboratories in the definition of applicable laboratories, we are soliciting public comments on that approach. Under such approach, the majority of Medicare revenues threshold and low expenditure threshold components of the definition of applicable laboratory would be determined at the CLIA certificate level instead of the NPI level. If we pursued such approach, we would have to modify the definition of applicable laboratory in § 414.502 to indicate that an applicable laboratory is one that holds a CLIA certificate under § 493.2 of the chapter. We would have concerns, however, about defining applicable laboratory by the CLIA certificate.

First, as we discussed in the CLFS final rule, given that information regarding the CLIA certificate is not required on the Form CMS-1450 14x bill type, which is the billing form used by hospitals for their laboratory outreach services, it is not clear how a hospital would identify and distinguish revenues generated by its separately CLIA-certified laboratories for their outreach services. We are interested in public comments regarding the mechanisms a hospital would need to develop to identify revenues if we used the CLIA certificate for purposes of determining applicable laboratory status, as well as comments about the administrative burden associated with developing such mechanisms.

In addition, we understand there could be a scenario where one CLIA certificate is assigned to a hospital's entire laboratory business, which would include laboratory tests performed for hospital patients as well as non-patients (that is, patients who are not admitted inpatients or registered outpatients of the hospital). For example, hospital laboratories with an outreach laboratory component would be assigned a single CLIA certificate if the hospital outreach laboratory has the same mailing address or location as the hospital laboratory. In this scenario, the majority of Medicare revenues threshold would be applied to the entire hospital laboratory, not just its outreach laboratory component. If a single CLIA certificate is assigned to the hospital's entire laboratory business, the hospital laboratory would be unlikely to meet the majority of Medicare revenues threshold because its laboratory revenues under the IPPS and OPFS alone would likely far exceed the revenues it receives under the CLFS and PFS. As a result, a hospital outreach laboratory that could otherwise meet the

definition of applicable laboratory, as currently defined at the NPI level, would not be an applicable laboratory if we were to require the CLIA certificate to define applicable laboratory. Given that this approach could have the effect of decreasing as opposed to increasing the number of applicable laboratories, we are requesting public comments on this potential drawback of defining applicable laboratory at the CLIA certificate level.

We believe that feedback on the topics discussed in this section could help inform us regarding potential refinements to the definition of applicable laboratory. We welcome comments on these topics from the public, including, physicians, laboratories, hospitals, and other interested stakeholders. We are especially interested in comments regarding the administrative burden of using the Form CMS-1450 14x bill type or CLIA certificate to identify applicable information attributed only to the hospital outreach laboratory portion of a hospital's total laboratory business. Depending on the comments we receive, it is possible we would consider approaches described in this section.

Again, we continue to believe that our current regulatory definitions and data collection processes are reasonable pursuant to governing law. The above public comments are solicited as part of the agency's ongoing engagement with stakeholders to receive the most up-to-date information and comments from those affected by the CLFS fee schedule.

5. Solicitation of Public Comments on the Low Expenditure Threshold in the Definition of Applicable Laboratory

a. Decreasing the Low Expenditure Threshold

In the CLFS final rule, we established a low expenditure threshold component in the definition of applicable laboratory at § 414.502, which is reflected in paragraph (4). To be an applicable laboratory, at least \$12,500 of an entity's Medicare revenues in a data collection period must be CLFS revenues (with the exception that there is no low expenditure threshold for an entity with respect to the ADLTs it furnishes). We established \$12,500 as the low expenditure threshold because we believed it achieved a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a test, and minimizing the reporting burden for laboratories that receive a relatively small amount of revenues under the CLFS. We indicated in the CLFS final rule (81 FR 41049) that once we

obtained applicable information under the new payment system, we may decide to reevaluate the low expenditure threshold in future years and propose a different threshold amount through notice and comment rulemaking.

Recently, we have heard from some laboratory stakeholders that the low expenditure threshold excludes most physician office laboratories and many small independent laboratories from reporting applicable information, and that by excluding so many laboratories, the payment rates under the new private payor rate-based CLFS reflect incomplete data, and therefore, inaccurate CLFS pricing.

As noted above, we discussed in the CLFS final rule that we believed a \$12,500 low expenditure threshold would reduce the reporting burden on small laboratories. In the CLFS final rule (81 FR 41051), we estimated that 95 percent of physician office laboratories and 55 percent of independent laboratories would not be required to report applicable information under our low expenditure criterion. Although we substantially reduced the number of laboratories qualifying as applicable laboratories (that is, approximately 5 percent of physician office laboratories and approximately 45 percent of independent laboratories), we estimated that the percentage of Medicare utilization would remain high. That is, approximately 5 percent of physician office laboratories would account for approximately 92 percent of CLFS spending on physician office laboratories and approximately 45 percent of independent laboratories would account for approximately 99 percent of CLFS spending on independent laboratories (81 FR 41051).

It is our understanding that physician offices are generally not prepared to identify, collect, and report each unique private payor rate from each private payor for each laboratory test code subject to the data collection and reporting requirements, and the volume associated with each unique private payor rate. As such, we believe revising the low expenditure threshold so that more physician office laboratories are required to report applicable information would likely impose significant administrative burdens on physician offices. We also believe that increasing participation from physician office laboratories would have minimal overall impact on payment rates given that the weighted median of private payor rates is dominated by the laboratories with the largest test volume. We note that our participation simulations from the first data reporting

period show that increasing the volume of physician office laboratories reporting applicable information has minimal overall impact on the weighted median of private payor rates. For more information on our participation simulations, please visit the CLFS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf>.

We continue to believe the current low expenditure threshold strikes an appropriate balance between collecting enough private payor rate data to accurately represent the weighted median of private payor rates while limiting the administrative burden on small laboratories. In addition, as discussed previously in this section, we are proposing to exclude MA plan revenues under Part C from total Medicare revenues in the definition of applicable laboratory, and if we finalize that proposal, we expect more laboratories of all types, including physician office laboratories, may meet the majority of Medicare revenues threshold.

However, we recognize from stakeholders that some physician office laboratories and small independent laboratories that are not applicable laboratories because they do not meet the current low expenditure threshold may still want to report applicable information despite the administrative burden associated with qualifying as an applicable laboratory. Therefore, we are seeking public comments on revising the low expenditure threshold to increase the level of participation among physician office laboratories and small independent laboratories. One approach could be for us to decrease the low expenditure threshold by 50 percent, from \$12,500 to \$6,250, in CLFS revenues during a data collection period. Under such approach, a laboratory would need to receive at least \$6,250 in CLFS revenues in a data collection period. If we were to adopt such an approach, we would need to revise paragraph (4) of the definition of applicable laboratory at § 414.502 to replace \$12,500 with \$6,250. We are seeking public comments on this approach.

We are particularly interested in comments from the physician community and small independent laboratories as to the administrative burden associated with such a revision to the low expenditure threshold. Specifically, we are requesting comments on the following issues: (1) Whether physician offices and small independent laboratories currently have

adequate staff levels to meet the data collection and data reporting requirements; (2) whether data systems are currently in place to identify, collect, and report each unique private payor rate from each private payor for each CLFS test code and the volume of tests associated with each unique private payor rate; (3) if physician offices and small independent laboratories are generally not prepared to conduct the data collection and data reporting requirements, what is the anticipated timeframe needed for physician office and small independent laboratories to be able to meet the data collection and data reporting requirements; and (4) any other administrative concerns that decreasing the low expenditure threshold may impose on offices and small independent laboratories.

b. Increasing the Low Expenditure Threshold

We recognize that many small laboratories may not want the additional administrative burden of data collection and reporting and, because their test volume is relatively low, their data is unlikely to have a meaningful impact on the weighted median of private payor rates for CDLTs under the CLFS. Mindful of stakeholder feedback from smaller laboratories that prefer to not be applicable laboratories because of the burden of collecting and reporting applicable information, we could increase the low expenditure threshold in the definition of applicable laboratory by 50 percent, from \$12,500 to \$18,750, in CLFS revenues during a data collection period. Because physician office laboratories would be less likely to meet a higher threshold, such approach would decrease the number of physician office laboratories and small independent laboratories required to collect and report applicable information. We expect decreasing the number of physician office laboratories and small independent laboratories reporting applicable information will have minimal impact on determining CLFS rates because we believe the largest laboratories with the highest test volumes will continue to dominate the weighted median of private payor rates.

If we were to adopt such an approach, we would need to revise paragraph (4) of the definition of applicable laboratory at § 414.502 to replace \$12,500 with \$18,750. We are seeking public comments on this approach. We are particularly interested in comments from the physician community and small independent laboratories on the administrative burden and relief of increasing the low expenditure

threshold. We believe that feedback on the topics discussed in this section will help inform us regarding potential refinements to the low expenditure threshold. We welcome comments on these topics from the public including, physicians, laboratories, hospitals, and other interested stakeholders. We are particularly interested in receiving comments from the physician community and small independent laboratories as to the administrative burden and relief associated with revisions to the low expenditure threshold. Depending on the comments we receive, it is possible we would consider approaches described in this section.

B. Proposed Changes to the Regulations Associated With the Ambulance Fee Schedule

1. Overview of Ambulance Services

a. Ambulance Services

Under the ambulance fee schedule, the Medicare program pays for ambulance transportation services for Medicare beneficiaries under Medicare Part B when other means of transportation are contraindicated by the beneficiary's medical condition and all other coverage requirements are met. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport.

These services include the following levels of service:

- For Ground—
- ++ Basic Life Support (BLS) (emergency and non-emergency)
- ++ Advanced Life Support, Level 1 (ALS1) (emergency and non-emergency)
- ++ Advanced Life Support, Level 2 (ALS2)
- ++ Paramedic ALS Intercept (PI)
- ++ Specialty Care Transport (SCT)
 - For Air—
 - ++ Fixed Wing Air Ambulance (FW)
 - ++ Rotary Wing Air Ambulance (RW)

b. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B (Supplemental Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition.

The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments

suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

c. Medicare Regulations for Ambulance Services

The regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations included at §§ 410.40 and 410.41. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare Part B.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), (Pub. L. 110–275) amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008, and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13)(A) of the Act have been extended several times. Most recently, section 50203(a)(1) of the Bipartisan

Budget Act of 2018 (BBA) (Pub. L. 115–123, enacted on February 9, 2018) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons through December 31, 2022. Thus, these payment add-ons apply to covered ground ambulance transports furnished before January 1, 2023. We are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For further information regarding the implementation of this provision for claims processing, please see CR 10531. For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439), the CY 2015 PFS final rule with comment period (79 FR 67743) and the CY 2016 PFS final rule with comment period (80 FR 71071 through 71072)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003) (MMA) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a “qualified rural area,” that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of

rural census tract). This rural bonus is sometimes referred to as the “Super Rural Bonus” and the qualified rural areas (also known as “super rural” areas) are identified during the claims adjudicative process via the use of a data field included in the CMS-supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Most recently, section 50203(a)(2) of the BBA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2022. Therefore, we are continuing to apply the 22.6 percent rural bonus described in this section (in the same manner as in previous years) to ground ambulance services with dates of service before January 1, 2023 where transportation originates in a qualified rural area. Accordingly, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For further information regarding the implementation of this provision for claims processing, please see CR 10531. For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74439 through 74440), CY 2015 PFS final rule with comment period (79 FR 67743 through 67744) and the CY 2016 PFS final rule with comment period (80 FR 71072)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary) through December 31, 2022, and does not require any substantive exercise of discretion on the part of the Secretary.

3. Amendment to Section 1834(l)(15) of the Act

Section 637 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub.L. 112–240), added section 1834(l)(15) of the Act to specify that the fee schedule amount otherwise applicable under the preceding provisions of section 1834(l) of the Act shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility. In the CY 2014 PFS final rule with comment period (78 FR 74440), we revised § 414.610 by adding paragraph (c)(8) to conform the regulations to this statutory requirement.

Section 53108 of the BBA amended section 1834(l)(15) of the Act to increase the reduction from 10 percent to 23 percent effective for ambulance services (as described in section 1834(l)(15) of the Act) furnished on or after October 1, 2018. The 10 percent reduction applies for ambulance services (as described in section 1834(l)(15) of the Act) furnished during the period beginning on October 1, 2013 and ending on September 30, 2018. Accordingly, we are proposing to revise § 414.610(c)(8) to conform the regulations to this statutory requirement.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate decrease, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for ambulance services described in section 1834(l)(15) of the Act furnished during the period beginning on October 1, 2013 and ending on September 30, 2018, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent, and for ambulance services described in section 1834(l)(15) of the Act furnished on or after October 1, 2018, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 23 percent. (For further information regarding application of this mandated rate decrease, please see CR 10549.)

C. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Payment for Care Management Services

In the CY 2018 PFS final rule, we revised the payment methodology for Chronic Care Management (CCM) services furnished by RHCs and FQHCs, and established requirements and payment for general Behavioral Health Integration (BHI) and psychiatric Collaborative Care Management (CoCM) services furnished in RHCs and FQHCs, beginning on January 1, 2018.

For CCM services furnished by RHCs or FQHCs between January 1, 2016, and December 31, 2017, payment is at the PFS national average payment rate for CPT 99490. For CCM, general BHI, and psychiatric CoCM services furnished by RHCs or FQHCs on or after January 1, 2018, we established 2 new HCPCS codes. The first HCPCS code, G0511, is a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month. The second HCPCS code, G0512, is a psychiatric CoCM

code for use by RHCs or FQHCs when at least 70 minutes of initial psychiatric CoCM services or 60 minutes of subsequent psychiatric CoCM services are furnished to a patient in a calendar month.

The payment amount for HCPCS code G0511 is set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. The 3 codes are CPT 99490 (20 minutes or more of CCM services), CPT 99487 (60 minutes or more of complex CCM services), and CPT 99484 (20 minutes or more of BHI services).

The payment amount for HCPCS code G0512 is set at the average of the 2 national non-facility PFS payment rates for CoCM codes and updated annually based on the PFS amounts. The 2 codes are CPT 99492 (70 minutes or more of initial psychiatric CoCM services) and CPT 99493 (60 minutes or more of subsequent psychiatric CoCM services).

For practitioners billing under the PFS, we are proposing for CY 2019 a new CPT code, 994X7, which would correspond to 30 minutes or more of CCM furnished by a physician or other qualified health care professional and is similar to CPT codes 99490 and 99487. For RHCs and FQHCs, we are proposing to add CPT code 994X7 as a general care management service and to include it in the calculation of HCPCS code G0511. That is, we propose that starting on January 1, 2019, RHCs and FQHC would be paid for G0511 based on the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 994X7.

We propose to revise § 405.2464 to reflect the current payment methodology that was finalized in the CY 2018 PFS and incorporate the addition of new CPT codes to HCPCS G0511.

2. Communication Technology-Based Services and Remote Evaluations

RHC and FQHC visits are face-to-face (in-person) encounters between a patient and an RHC or FQHC practitioner during which time one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, nurse practitioners, physician assistants, certified nurse midwives, clinical psychologists, and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient. A Transitional Care Management service can also be an RHC or FQHC visit. A Diabetes Self-Management Training (DSMT) service or a Medical Nutrition Therapy (MNT)

service furnished by a certified DSMT or MNT provider may also be an FQHC visit.

RHCs are paid an all-inclusive rate (AIR) for medically-necessary, face-to-face visits with an RHC practitioner. The rate is subject to a payment limit, except for those RHCs that have an exception to the payment limit for being "provider-based" (see § 413.65). FQHCs are paid the lesser of their charges or the FQHC Prospective Payment System (PPS) rate for medically-necessary, face-to-face visits with an FQHC practitioner. Only medically-necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner can be RHC or FQHC billable visits.

The RHC and FQHC payment rates reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day, and are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care.

Services furnished by auxiliary personnel (such as nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment. This may include services furnished prior to or after the billable visit that occur within a medically appropriate time period, which is usually 30 days or less.

RHCs and FQHCs are also paid for care management services, including chronic care management services, general behavioral health integration services, and psychiatric Collaborative Care Model services. These are typically non-face-to-face services that do not require the skill level of an RHC or FQHC practitioner and are not included in the RHC or FQHC payment methodologies.

For practitioners billing under the PFS, we are proposing for CY 2019 separate payment for certain communication technology-based services. This includes what is referred to as "Brief Communication Technology-based Service" for a "virtual check-in" and separate payment for remote evaluation of recorded video and/or images. The "virtual check-in" visit would be billable when a physician or non-physician practitioner has a brief (5 to 10 minutes), non-face-to-face check in with a patient via communication technology to assess whether the patient's condition necessitates an office visit. This service could be billed only in situations where the medical

discussion was for a condition not related to an E/M service provided within the previous 7 days, and does not lead to an E/M service or procedure within the next 24 hours or at the soonest available appointment. We are also proposing payment for practitioners billing under the PFS for remote evaluation services. This payment would be for the remote evaluation of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology, including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment. Both of these services would be priced under the PFS at a rate that reflects the resource costs of these non-face-to-face services relative to other PFS services, including face-to-face and in-person visits.

The RHC and FQHC payment models are distinct from the PFS model in that the payment is for a comprehensive set of services and supplies associated with an RHC or FQHC visit. A direct comparison between the payment for a specific service furnished in an RHC or FQHC and the same service furnished in a physician's office is not possible, because the payment for RHCs and FQHCs is a per diem payment that includes the cost for all services and supplies rendered during an encounter, and payment for a service furnished in a physician's office and billed under the PFS is only for that service.

We recognize that there are occasions when it may be beneficial to both the patient and the RHC or FQHC to utilize communications-based technology to determine the course of action for a health issue. Currently under the RHC and FQHC payment systems, if the communication results in a face-to-face billable visit with an RHC or FQHC practitioner, the cost of the prior communication would be included in the RHC AIR or the FQHC PPS. However, if as a result of the communication it is determined that a visit is not necessary, there would not be a billable visit and there would be no payment.

RHCs and FQHCs furnish services in rural and urban areas that have been determined to be medically underserved areas or health professional shortage areas. They are an integral component of the Nation's health care safety net, and we want to assure that Medicare patients who are served by RHCs and FQHCs are able to communicate with their RHC or FQHC practitioner in a

manner that enhances access to care, consistent with evolving medical care. Particularly in rural areas where transportation is limited and distances may be far, we believe the use of communication technology may help some patients to determine if they need to schedule a visit at the RHC or FQHC. If it is determined that a visit is not necessary, the RHC or FQHC practitioner would be available for other patients who need their care.

When communication-based technology services are furnished in association with an RHC or FQHC billable visit, the costs of these services are included in the RHC AIR or the FQHC PPS and are not separately billable. However, if there is no RHC or FQHC billable visit, these costs are not paid as part of an RHC AIR or FQHC PPS payment. We are therefore proposing that, effective January 1, 2019, RHCs and FQHCs receive an additional payment for the costs of communication technology-based services or remote evaluation services that are not already captured in the RHC AIR or the FQHC PPS payment when the requirements for these services are met.

We propose that RHCs and FQHCs receive payment for communication technology-based services or remote evaluation services when at least 5 minutes of communications-based technology or remote evaluation services are furnished by an RHC or FQHC practitioner to a patient that has been seen in the RHC or FQHC within the previous year. These services may only be billed when the medical discussion or remote evaluation is for a condition not related to an RHC or FQHC service provided within the previous 7 days, and does not lead to an RHC or FQHC service within the next 24 hours or at the soonest available appointment, since in those situation the services are already paid as part of the RHC or FQHC per-visit payment.

We propose to create a new Virtual Communications G code for use by RHCs and FQHCs only, with a payment rate set at the average of the PFS national non-facility payment rates for HCPCS code GVC11 for communication technology-based services, and HCPCS code GRAS1 for remote evaluation services. RHCs and FQHCs would be able to bill the Virtual Communications G-code either alone or with other payable services. The payment rate for the Virtual Communications G-code would be updated annually based on the PFS amounts.

We also propose to waive the RHC and FQHC face-to-face requirements when these services are furnished to an

RHC or FQHC patient. Coinsurance would be applied to FQHC claims, and coinsurance and deductibles would apply to RHC claims for these services. Services that are currently being furnished and paid under the RHC AIR or FQHC PPS payment methodology will not be affected by the ability of the RHC or FQHC to receive payment for additional services that are not included in the RHC AIR or FQHC PPS.

3. Other Options Considered

We considered other options for payment for these services. First, we considered adding communication technology-based and remote evaluation services as an RHC or FQHC stand-alone service. Under this option, payment for RHCs would be at the AIR, and payment for FQHCs would be the lesser of total charges or the PPS rate. We are not proposing this payment option because these services do not meet the requirements for an RHC or FQHC billable visit and payment at the RHC AIR or FQHC PPS would result in a payment rate incongruent with efficiencies inherent in the provision of the technology-based services.

The second option we considered was to allow RHCs and FQHCs to bill HCPCS codes GVC11 or GRAS1 separately on an RHC or FQHC claim. We are not proposing this payment option because we believe that a combined G code is less burdensome and will allow expansion of these services without adding additional codes on an RHC or FQHC claim.

We invite comments on this proposal. In particular, we are interested in comments regarding the appropriateness of payment for communication technology-based and remote evaluation services in the absence of an RHC or FQHC visit, the burden associated with documentation for billing these codes (RHC or FQHC practitioner's time, medical records, etc.), and any potential impact on the per diem nature of RHC and FQHC billing and payment structure as a result of payment for these services. We are also seeking public comment on whether it would be clinically appropriate to apply a frequency limitation on the use of the new Virtual Communications G code by the same RHC or FQHC with the same patient, and on what would be a reasonable frequency limitation to ensure that this code is appropriately utilized.

4. Other Regulatory Updates

In addition to the regulatory change described in this section of the rule, we propose the following for accuracy:

- Removal of the extra section mark in the definition of "Federally qualified health center (FQHC)" in § 405.2401.
- Replacing the word "his" with "his or her" in the definition of "Secretary" in § 405.2401.

D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access to Medicare Act (PAMA) amended Title XVIII of the Act to add section 1834(q) of the Act directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The CY 2016 PFS final rule with comment period addressed the initial component of the new Medicare AUC program, specifying applicable AUC. In that rule (80 FR 70886), we established an evidence-based process and transparency requirements for the development of AUC, defined provider-led entities (PLEs) and established the process by which PLEs may become qualified to develop, modify or endorse AUC. The first list of qualified PLEs was posted on the CMS website at the end of June 2016 at which time their AUC libraries became specified applicable AUC for purposes of section 1834(q)(2)(A) of the Act. The CY 2017 PFS final rule addressed the second component of this program, specification of qualified clinical decision support mechanisms (CDSMs). In the CY 2017 PFS final rule (81 FR 80170), we defined CDSM, identified the requirements CDSMs must meet for qualification, including preliminary qualification for mechanisms documenting how and when each requirement is reasonably expected to be met, and established a process by which CDSMs may become qualified. We also defined applicable payment systems under this program, specified the first list of priority clinical areas, and identified exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services. The first list of qualified CDSMs was posted on the CMS website in July 2017.

The CY 2018 PFS final rule addressed the third component of this program, the consultation and reporting requirements. In the CY 2018 PFS final rule (82 FR 53190), we established the start date of January 1, 2020 for the Medicare AUC program for advanced diagnostic imaging services. It is for services ordered on and after this date that ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services, and furnishing professionals must report

AUC consultation information on the Medicare claim. We further specified that the AUC program will begin on January 1, 2020 with a year-long educational and operations testing period during which time claims will not be denied for failure to include proper AUC consultation information. We also established a voluntary period from July 2018 through the end of 2019 during which ordering professionals who are ready to participate in the AUC program may consult specified applicable AUC through qualified CDSMs and communicate the results to furnishing professionals, and furnishing professionals who are ready to do so may report AUC consultation information on the claim (<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10481.pdf>). Additionally, to incentivize early use of qualified CDSMs to consult AUC, we established in the CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstances Policy for the Transition Year final rule with comment period and interim final rule (hereinafter "CY 2018 Quality Payment Program final rule") a high-weight improvement activity for ordering professionals who consult specified AUC using a qualified CDSM for the Merit-based Incentive Payment System (MIPS) performance period that began January 1, 2018 (82 FR 54193).

This rule proposes additions to the definition of applicable setting, clarification around who may perform the required AUC consultation using a qualified CDSM under this program, clarification that reporting is required across claim types and by both the furnishing professional and furnishing facility, changes to the policy for significant hardship exceptions for ordering professionals under this program, mechanisms for claims-based reporting, and a solicitation of feedback regarding the methodology to identify outlier ordering professionals.

1. Background

AUC present information in a manner that links: A specific clinical condition or presentation; one or more services; and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual clinical presentation. For purposes of this program AUC is a set or library of individual appropriate use criteria. Each individual criterion is

an evidence-based guideline for a particular clinical scenario based on a patient's presenting symptoms or condition.

AUC need to be integrated as seamlessly as possible into the clinical workflow. CDSMs are the electronic portals through which clinicians access the AUC during the patient workup. They can be standalone applications that require direct entry of patient information, but may be more effective when they are integrated into Electronic Health Records (EHRs). Ideally, practitioners would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.

2. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, "Recognizing Appropriate Use Criteria for Certain Imaging Services," which directs the Secretary to establish a new program to promote the use of AUC. Section 1834(q)(4) of the Act requires ordering professionals to consult with specified applicable AUC through a qualified CDSM for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system; and payment for such service may only be made if the claim for the service includes information about the ordering professional's consultation of specified applicable AUC through a qualified CDSM.

3. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, and each component has its own implementation date: (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2) of the Act); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3) of the Act); (3) AUC consultation by ordering professionals, and reporting on AUC consultation by January 1, 2017 (section 1834(q)(4) of the Act); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5) of the Act). We did not identify mechanisms for consultation by April 1, 2016. Therefore, we did not require ordering professionals to consult CDSMs or furnishing professionals to report information on the consultation by the January 1, 2017 date.

a. Establishment of AUC

In the CY 2016 PFS final rule with comment period, we addressed the first component of the Medicare AUC program under section 1834(q)(2) of the

Act—the requirements and process for establishment and specification of applicable AUC, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term PLE (provider-led entity) and finalizing requirements for the rigorous, evidence-based process by which a PLE would develop AUC, upon which qualification is based, as provided in section 1834(q)(2)(B) of the Act and in the CY 2016 PFS final rule with comment period. Using this process, once a PLE is qualified by CMS, the AUC that are developed, modified or endorsed by the qualified PLE are considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act. We defined PLE to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the High Value Healthcare Collaborative or the National Comprehensive Cancer Network. Qualified PLEs may collaborate with third parties that they believe add value to their development of AUC, provided such collaboration is transparent. We expect qualified PLEs to have sufficient infrastructure, resources, and the relevant experience to develop and maintain AUC according to the rigorous, transparent, and evidence-based processes detailed in the CY 2016 PFS final rule with comment period.

In the same rule we established a timeline and process under § 414.94(c)(2) for PLEs to apply to become qualified. Consistent with this timeline the first list of qualified PLEs was published at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/PLE.html> in June 2016 (OMB Control Number 0938–1288).

b. Mechanism for AUC Consultation

In the CY 2017 PFS final rule, we addressed the second major component of the Medicare AUC program—the specification of qualified CDSMs for use by ordering professionals for consultation with specified applicable AUC under section 1834(q)(3) of the Act, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term CDSM and finalizing functionality requirements of mechanisms, upon which qualification is based, as provided in section 1834(q)(3)(B) of the Act and in the CY 2017 PFS final rule. CDSMs may receive full qualification or preliminary qualification if most, but not all, of the requirements are met at the time of application. The preliminary qualification period began June 30, 2017

and ends when the AUC consulting and reporting requirements become effective on January 1, 2020. The preliminarily qualified CDSMs must meet all requirements by that date. We defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. Tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology or a mechanism established by the Secretary.

In the CY 2017 PFS final rule, we established a timeline and process in § 414.94(g)(2) for CDSM developers to apply to have their CDSMs qualified. Consistent with this timeline, the first list of qualified CDSMs was published at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html> in July 2017 (OMB Control Number 0938–1315).

c. AUC Consultation and Reporting

In the CY 2018 PFS final rule, we addressed the third major component of the Medicare AUC program—consultation with applicable AUC by the ordering professional and reporting of such consultations under section 1834(q)(4) of the Act. We established a January 1, 2020 effective date for the AUC consultation and reporting requirements for this program. We also established a voluntary period during which early adopters can begin reporting limited consultation information on Medicare claims from July 2018 through December 2019. During the voluntary period there is no requirement for ordering professionals to consult AUC or furnishing professionals to report information related to the consultation. On January 1, 2020, the program will begin with an educational and operations testing period and during this time we will continue to pay claims whether or not they correctly include AUC consultation information. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020; and furnishing professionals must report the AUC consultation information on the Medicare claim for these services ordered on or after January 1, 2020.

Consistent with section 1834(q)(4)(B) of the Act, we also established that furnishing professionals must report the

following information on Medicare claims for advanced diagnostic imaging services as specified in section 1834(q)(1)(C) of the Act and defined in § 414.94(b), furnished in an applicable setting as defined in section 1834(q)(1)(D) of the Act, paid for under an applicable payment system as defined in section 1834(q)(4)(D) of the Act, and ordered on or after January 1, 2020: (1) The qualified CDSM consulted by the ordering professional; (2) whether the service ordered would or would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional). Proposed clarifying revisions to the reporting requirement are discussed later in this preamble.

Section 1834(q)(4)(C) of the Act provides for exceptions to the AUC consultation and reporting requirements in the case of: A service ordered for an individual with an emergency medical condition, a service ordered for an inpatient and for which payment is made under Medicare Part A, and a service ordered by an ordering professional for whom the Secretary determines that consultation with applicable AUC would result in a significant hardship. In the CY 2017 PFS final rule, we adopted a regulation at § 414.94(h)(1)(i) to specify the circumstances under which AUC consultation and reporting requirements are not applicable. These include applicable imaging services ordered: (1) For an individual with an emergency medical condition (as defined in section 1867(e)(1) of the Act); (2) for an inpatient and for which payment is made under Medicare Part A; and (3) by an ordering professional who is granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year under 42 CFR 495.102(d)(4), except for those granted under § 495.102(d)(4)(iv)(C). We are proposing changes to the conditions for significant hardship exceptions, and our proposals are discussed later in this preamble. We remind readers that consistent with section 1834(q)(4)(A) of the Act, ordering professionals must consult AUC for every applicable imaging service furnished in an applicable setting and paid under an applicable payment system unless a statutory exception applies.

Section 1834(q)(4)(D) of the Act specifies the applicable payment systems for which AUC consultation and reporting requirements apply and, in the CY 2017 PFS final rule, consistent

with the statute, we defined applicable payment system in our regulation at § 414.94(b) as: (1) The PFS established under section 1848(b) of the Act; (2) the prospective payment system for hospital outpatient department services under section 1833(t) of the Act; and (3) the ambulatory surgical center payment system under section 1833(i) of the Act.

Section 1834(q)(1)(D) of the Act specifies the applicable settings in which AUC consultation and reporting requirements apply: A physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other "provider-led outpatient setting determined appropriate by the Secretary." In the CY 2017 PFS final rule, we added this definition to our regulation at § 414.94(b). Proposed additional applicable settings are discussed later in this preamble.

d. Identification of Outliers

The fourth component of the Medicare AUC program is specified in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement that applies for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. Because we established a start date of January 1, 2020 for AUC consultation and reporting requirements, we will not have identified any outlier ordering professionals by that date. As such, implementation of the prior authorization component is delayed. However, we did finalize in the CY 2017 PFS final rule the first list of priority clinical areas to guide identification of outlier ordering professionals as follows:

- Coronary artery disease (suspected or diagnosed).
- Suspected pulmonary embolism.
- Headache (traumatic and non-traumatic).
- Hip pain.
- Low back pain.
- Shoulder pain (to include suspected rotator cuff injury).
- Cancer of the lung (primary or metastatic, suspected or diagnosed).
- Cervical or neck pain.

We are not including proposals to expand or modify the list of priority clinical areas in this proposed rule.

4. Proposals for Continuing Implementation

We propose to amend § 414.94 of our regulations, "Appropriate Use Criteria

for Certain Imaging Services," to reflect the following proposals.

a. Expanding Applicable Settings

Section 1834(q)(1)(D) of the Act specifies that the AUC consultation and reporting requirements apply only in an applicable setting, which means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. In the CY 2017 PFS final rule, we codified this definition in § 414.94(b). We are proposing to revise the definition of applicable setting to add an independent diagnostic testing facility (IDTF).

We believe the addition of IDTFs to the definition of applicable setting will ensure that the AUC program is in place across outpatient settings in which outpatient advanced diagnostic imaging services are furnished. IDTFs furnish services for a large number of Medicare beneficiaries; nearly \$1 billion in claims for 2.4 million beneficiaries in 2010 (OEI-05-09-00560). An IDTF is independent of a hospital or physician's office and diagnostic tests furnished by an IDTF are performed by licensed, certified non-physician personnel under appropriate physician supervision (§ 410.33). Like other applicable settings, IDTFs must meet the requirements specified in § 410.33 of our regulations to be enrolled to furnish and bill for advanced diagnostic imaging and other IDTF services. Services that may be provided by an IDTF include, but are not limited to, magnetic resonance imaging (MRI), ultrasound, x-rays, and sleep studies. An IDTF may be a fixed location, a mobile entity, or an individual non-physician practitioner, and diagnostic procedures performed by an IDTF are paid under the PFS. IDTF services must be furnished under the appropriate level of physician supervision as specified in § 410.33(b); and all procedures furnished by the IDTF must be ordered in writing by the patient's treating physician or non-physician practitioner. As such, we believe the IDTF setting is a provider-led outpatient setting appropriate for addition to the list of applicable settings under section 1834(q)(1)(D), and we propose to add IDTF to our definition of applicable setting under § 414.94(b) of the regulations.

We note that under the PFS, payment for many diagnostic tests including the advanced diagnostic imaging services to which the AUC program applies can be made either "globally" when the entire

service is furnished and billed by the same entity; or payment can be made separately for the technical component (TC) of the service and the professional component (PC) when those portions of the service are furnished and billed by different entities. In general, the TC for an advanced diagnostic imaging service is the portion of the test during which the patient is present and the image is captured. The PC is the portion of the test that involves a physician's interpretation and report on the captured image. For example, when a CT scan is ordered by a patient's treating physician, the entire test (TC and PC) could be furnished by a radiologist in their office and billed as a "global" service. Alternatively, the TC could be furnished and billed by an IDTF, and the PC could be furnished and billed by a radiologist in private practice. By adding IDTFs as an applicable setting, we believe we would appropriately and consistently apply the AUC program across the range of outpatient settings where applicable imaging services are furnished.

We propose to revise the definition of applicable setting under § 414.94(b) to include an IDTF. We invite comments on this proposal and on the possible inclusion of any other applicable setting. We remind commenters that application of the AUC program is not only limited to applicable settings, but also to services for which payment is made under applicable payment systems (the physician fee schedule, the OPPS, and the ASC payment system).

b. Consultations by Ordering Professionals

Section 1834(q)(1)(E) of the Act defines the term "ordering professional" as a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who orders an applicable imaging service. The AUC consultation requirement applies to these ordering professionals. We are proposing that the consultation with AUC through a qualified CDSM may be performed by clinical staff working under the direction of the ordering professional, subject to applicable State licensure and scope of practice law, when the consultation is not performed personally by the ordering professional whose NPI will be listed on the order for an advanced imaging service.

In response to the CY 2018 PFS proposed rule, we received several public comments requesting clarification regarding who is required to perform the consultation of AUC through a qualified CDSM. Commenters not only sought clarification, but also provided recommendations for

requirements around this topic. Some commenters recommended that CMS strictly interpret the statutory language and only allow the clinician placing the order to perform the consultation and others recommended that CMS allow others to perform the AUC consultation on behalf of the clinician.

Section 1834(q)(4)(A)(i) of the Act requires an ordering professional to consult with a qualified CDSM, and this was codified in our regulations at § 414.94(j). The statute does not explicitly provide for consultations under the AUC program to be fulfilled by other professionals, individuals or organizations on behalf of the ordering professional; however, we continue to seek ways to minimize the burden of this new Medicare program and understand that many practices currently use clinical staff, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation and subsequent ordering of advanced diagnostic imaging. Therefore, we propose to modify paragraph § 414.94(j) to specify that additional individuals may perform the required AUC consultation.

When the AUC consultation is not performed personally by the ordering professional, we propose the consultation may be performed by auxiliary personnel incident to the ordering physician or non-physician practitioner's professional service. We believe this approach is appropriate under this program and still accomplishes the goal of promoting the use of AUC. This proposed policy would allow the ordering professional to exercise their discretion to delegate the performance of this consultation. It is important to note that the ordering professional is ultimately responsible for the consultation as their NPI is reported by the furnishing professional on the claim for the applicable imaging service; and that it is the ordering professional who could be identified as an outlier ordering professional and become subject to prior authorization based on their ordering pattern.

We propose to revise the AUC consultation requirement specified at § 414.94(j) to specify that the AUC consultation may be performed by auxiliary personnel under the direction of the ordering professional and incident to the ordering professional's services.

c. Reporting AUC Consultation Information

Section 1834(q)(4)(B) of the Act requires that payment for an applicable imaging service furnished in an applicable setting and paid for under an

applicable payment system may only be made if the claim for the service includes certain information about the AUC consultation. As such, the statute requires that AUC consultation information be included on any claim for an outpatient advanced diagnostic imaging service, including those billed and paid under any applicable payment system (the PFS, OPPS or ASC payment system). When we initially codified the AUC consultation reporting requirement in § 414.94(k) through rulemaking in the CY 2018 PFS final rule, we specified only that "furnishing professionals" must report AUC consultation information on claims for applicable imaging services. This led some stakeholders to believe that AUC consultation information would be required only on practitioner claims. To better reflect the statutory requirements of section 1834(q)(4)(B) of the Act, we are proposing to revise our regulations to clarify that AUC consultation information must be reported on all claims for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system. The revised regulation would more clearly express the scope of advanced diagnostic imaging services that are subject to the AUC program, that is, those furnished in an applicable setting and paid under an applicable payment system.

The language codified in § 414.94(k) uses the term furnishing professional to describe who must report the information on the Medicare claims. We recognize that section 1834(q)(1)(F) of the Act specifies that a "furnishing professional" is a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who furnishes an applicable imaging service. However, because section 1834(q)(4)(B) of the Act, as described above, clearly includes all claims paid under applicable payment systems without exclusion, we believe that the claims from both furnishing professionals and facilities must include AUC consultation information. In other words, we would expect this information to be included on the practitioner's claim for the professional component of the applicable advanced diagnostic imaging service and on the provider's or supplier's claim for the facility portion or TC of the imaging service.

As such, we propose to revise § 414.94(k) to clearly reflect the scope of claims for which AUC consultation information must be reported, and to clarify that the requirement to report AUC consultation information is not limited to the furnishing professional.

d. Claims-Based Reporting

In the CY 2018 PFS proposed rule (82 FR 34094) we discussed using a combination of G-codes and modifiers to report the AUC consultation information on the Medicare claim. We received numerous public comments objecting to this potential solution. In the 2018 PFS final rule, we agreed with many of the commenters that additional approaches to reporting AUC consultation information on Medicare claims should be considered, and we learned from many commenters that reporting a unique consultation identifier (UCI) would be a less burdensome and preferred approach. The UCI would include all the information required under section 1834(q)(4)(B) of the Act including an indication of AUC adherence, non-adherence and not applicable responses. Commenters noted that capturing a truly distinguishing UCI on the claim will allow for direct mapping from a single AUC consultation to embedded information within a CDSM. We indicated that we would work with stakeholders to further explore the concept of using a UCI to satisfy the requirements of section 1834(q)(4)(B) of the Act, which will be used for Medicare claims processing and, ultimately, for the identification of outlier ordering professionals, and consider developing a taxonomy for a UCI.

We had the opportunity to engage with some stakeholders over the last 6 months and we understand that some commenters from the previous rule continue to be in favor of a UCI, while some may have changed their position upon further consideration.

We provide the following information to summarize alternatives we considered. CMS had originally considered assigning a G-code for every qualified CDSM with a code descriptor containing the name of the qualified CDSM. The challenge to this approach arises when there is more than one advanced imaging service on a single claim. CMS could attribute a single G-code to all of the applicable imaging services for the patient's clinical condition on the claim, which might be appropriate if each AUC consultation for each service was through the same CDSM. If a different CDSM was used for each service (for example, when services on a single claim were ordered by more than one ordering professional and each ordering professional used a different CDSM) then multiple G-codes could be needed on the claim. Each G-code would appear on the claim individually as its own line item. As a

potential solution, we considered the use of modifiers, which are appealing because they would appear on the same line as the CPT code that identifies the specific billed service. Therefore, information entered onto a claim would arrive into the claims processing system paired with the relevant AUC consultation information.

When reporting the required AUC consultation information based on the response from a CDSM: (1) The imaging service would adhere to the applicable AUC; (2) the imaging service would not adhere to such criteria; or (3) such criteria were not applicable to the imaging service ordered, three modifiers could be developed. These modifiers, when placed on the same line with the CPT code for the advanced imaging service would allow this information to be easily accessed in the Medicare claims data and matched with the imaging service.

Stakeholders have made various suggestions for a taxonomy that could be used to develop a UCI to report the required information. Stakeholders have also considered where to place the UCI on the claim. We understand the majority of solutions suggested by stakeholders involving a UCI are claim-level solutions and would not allow CMS to attribute the CDSM used or the AUC adherence status (adherent or not adherent, or not applicable) to a specific imaging service. As such, the approach of using a UCI would not identify whether an AUC consultation was performed for each applicable imaging service reported on a claim form, or be useful for purposes of identifying outlier ordering professionals in accordance with section 1834(q)(5) of the Act.

We have received ideas from stakeholders that are both for and against the two approaches we have identified; and we appreciate the stakeholders that have provided additional information or engaged us in this discussion. Internally, we have explored the possibility of using and feasibility of developing a UCI, and concluded that, although we initiated this approach during the CY 2018 PFS final rule, it is not feasible to create a uniform UCI taxonomy, determine a location of the UCI on the claims forms, obtain the support and permission by national bodies to use claim fields for this purpose, and solve the underlying issue that the UCI seems limited to claim-level reporting. Using coding structures that are already in place (such as G-codes and modifiers) would allow CMS to establish reporting requirements prior to the start of the program (January 1, 2020).

Since we did not finalize a proposal in the CY 2018 PFS final rule, we propose in this rule to use established coding methods, to include G-codes and modifiers, to report the required AUC information on Medicare claims. This will allow the program to be implemented by January 1, 2020. We will consider future opportunities to use a UCI and look forward to continued engagement with and feedback from stakeholders.

e. Significant Hardship Exception

We are proposing to revise § 414.94(i)(3) of our regulations to adjust the significant hardship exception requirements under the AUC program. We are proposing criteria specific to the AUC program and independent of other programs. An ordering professional experiencing any of the following when ordering an advanced diagnostic imaging service would not be required to consult AUC using a qualified CDSM, and the claim for the applicable imaging service would not be required to include AUC consultation information. The proposed criteria include:

- Insufficient internet access;
- EHR or CDSM vendor issues; or
- Extreme and uncontrollable circumstances.

Insufficient internet access is specific to the location where an advanced diagnostic imaging service is ordered by the ordering professional. EHR or CDSM vendor issues may include situations where ordering professionals experience temporary technical problems, installation or upgrades that temporarily impede access to the CDSM, vendors cease operations, or CMS de-qualifies a CDSM. CMS expects these situations to generally be irregular and unusual. Extreme and uncontrollable circumstances include disasters, natural or man-made, that have a significant negative impact on healthcare operations, area infrastructure or communication systems. These could include areas where events occur that have been designated a Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary. Based on 2016 data from the Medicare EHR Incentive Program and the 2019 payment year MIPS eligibility and special status file, we estimate that 6,699 eligible clinicians could submit such a request due to extreme and uncontrollable circumstances or as a result of a decertification of an EHR, which represents less than 1-percent of available ordering professionals.

In the CY 2017 PFS final rule, for purposes of the AUC program significant hardship exceptions, we

provided that those who received significant hardship exceptions in the following categories from § 495.102(d)(4) would also qualify for significant hardship exceptions for the AUC program:

- Insufficient Internet Connectivity (as specified in § 495.102(d)(4)(i)).
- Practicing for less than 2 years (as specified in § 495.102(d)(4)(ii)).
- Extreme and Uncontrollable Circumstances (as specified in § 495.102(d)(4)(iii)).
- Lack of Control over the Availability of CEHRT (as specified in § 495.102(d)(4)(iv)(A)).
- Lack of Face-to-Face Patient Interaction (as specified in § 495.102(d)(4)(iv)(B)).

In the CY 2018 PFS proposed rule, we proposed to amend the AUC significant hardship exception regulation to specify that ordering professionals who are granted reweighting of the Advancing Care Information (ACI) performance category to zero percent of the final score for the year under MIPS per § 414.1380(c)(2) due to circumstances that include the criteria listed in § 495.102(d)(4)(i), (d)(4)(iii), and (d)(4)(iv)(A) and (B) (as outlined in the bulleted list above) would be excepted from the AUC consultation requirement during the same year that the reweighting applies for purposes of the MIPS payment adjustment. This proposal removed § 495.102(d)(4)(ii), practicing for less than 2 years, as a criterion since these clinicians are not MIPS eligible clinicians and thus would never meet the criteria for reweighting of their MIPS ACI performance category for the year.

In response to public comments, we did not finalize the proposed changes to the significant hardship exceptions in the CY 2018 PFS final rule and instead decided further evaluation was needed before moving forward with any modifications. As we have continued to evaluate both policy options and operational considerations for the AUC significant hardship exception, we have concluded that the most appropriate approach, which we consider to be more straightforward and less burdensome than the current approach, involves establishing significant hardship criteria and a process that is independent from other Medicare programs. Our original intention was to design the AUC significant hardship exception process in alignment with the process for the Medicare EHR Incentive Program for eligible professionals, and then for the MIPS ACI (now Promoting Interoperability) performance category. Under section 1848(a)(7)(A) of the Act, the downward payment adjustment for

eligible professionals under the Medicare EHR Incentive Program will end in 2018, and we are unable to continue making reference to a regulation relating to a program that is no longer in effect. We also note as we have in the past that the AUC program is a real-time program with a need for real-time significant hardship exceptions. This is in contrast to the way significant hardship exceptions are handled under MIPS where the hardship might impact some or all of a performance period, or might impact reporting, both of which occur well before the MIPS payment adjustment is applied in a subsequent year. We recognize that when a significant hardship arises, an application process to qualify for an exception becomes a time consuming hurdle for health care providers to navigate, and we believe that it is important to minimize the burden involved in seeking significant hardship exceptions. As such, we are proposing that ordering professionals would self-attest if they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order and such attestation be supported with documentation of significant hardship. Ordering professionals attesting to a significant hardship would communicate that information, along with the AUC consultation information, to the furnishing professional with the order and it would be reflected on the furnishing professional's and furnishing facility's claim by appending a HCPCS modifier. The modifier would indicate that the ordering professional has self-attested to experiencing a significant hardship and communicated this to the furnishing professional with the order. Claims for advanced diagnostic imaging services that include a significant hardship exception modifier would not be required to include AUC consultation information.

In addition to the proposals above, we invite the public to comment on any additional circumstances that would cause the act of consulting AUC to be particularly difficult or challenging for the ordering professional, and for which it may be appropriate for an ordering professional to be granted a significant hardship exception under the AUC program. While we understand the desire by some for significant hardship categories unrelated to difficulty in consulting AUC through a CDSM, we remind readers that circumstances that are not specific to AUC consultation, such as the ordering professional being in clinical practice for a short period of time or having limited numbers of

Medicare patients, would not impede clinicians from consulting AUC through a CDSM as required to meet the requirements of this program.

f. Identification of Outliers

As previously mentioned, the fourth component of the AUC program specified in section 1834(q)(5) of the Act, is the identification of outlier ordering professionals. In our efforts to start a dialogue with stakeholders, we would like to invite the public to submit their ideas on a possible methodology for the identification of outlier ordering professionals who would eventually be subject to a prior authorization process when ordering advanced diagnostic imaging services. Specifically, we are soliciting comments on the data elements and thresholds that CMS should consider when identifying outliers. We also intend to perform and use analysis to assist us in developing the outlier methodology for the AUC program. Our existing prior authorization programs generally do not specifically focus on outliers. We are interested in hearing ideas from the public on how outliers could be determined for the AUC program. Because we would be concerned about data integrity and reliability, we do not intend to include data from the educational and operations testing period in CY 2020 in the analysis used to develop our outlier methodology. Since we intend to evaluate claims data to inform our methodology we expect to address outlier identification and prior authorization more fully in CY 2022 or 2023 rulemaking. As noted above, we expect to solicit public comment to inform our methodology through rulemaking before finalizing our approach.

We note that we may not provide comprehensive comment summaries and responses to comments submitted in response to this solicitation. Rather, we will actively consider all input as we develop the methodology for the identification of outliers.

5. Summary

Section 1834(q) of the Act includes rapid timelines for establishing a Medicare AUC program for advanced diagnostic imaging services. The impact of this program is extensive as it will apply to every physician or other practitioner who orders or furnishes advanced diagnostic imaging services (for example, MRI, computed tomography (CT) or positron emission tomography (PET)). This crosses almost every medical specialty and could have a particular impact on primary care

physicians since their scope of practice can be quite broad.

We continue to believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and CDSM developers. It is for these reasons we propose to continue a stepwise approach, adopted through notice and comment rulemaking.

In summary, we are proposing policies to modify existing requirements and criteria and to provide further clarification on implementation of the AUC program. We include a proposal to add IDTFs to the definition of applicable settings under this program. We also include proposals regarding who beyond the ordering professional may consult AUC through a qualified CDSM to meet the statutory requirements for the AUC program, as well as a proposal to more clearly include all entities required to report AUC consultation information on the claim. Finally, we propose to modify the significant hardship exception criteria and process under § 414.94(i)(3) to be specific to the AUC program and independent of other Medicare programs. We are also requesting public comment on other circumstances that could be considered significant hardships, posing particular real-time difficulty or challenge to the ordering professional in consulting AUC. We invite the public to submit comments on these proposals, as well as provide comment on potential methods for, and issues related to, mechanisms for claims-based reporting and identifying outlier ordering professionals.

We will continue to post information on our website for this program, accessible at www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html.

E. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

1. Background

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for the incentive payments made to Medicaid EPs and eligible hospitals for the adoption, implementation, upgrade, and meaningful use of CEHRT. We have implemented these statutory provisions in prior rulemakings to establish the Medicaid Promoting Interoperability Programs.

Under sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C)(i)(II) of the Act, and the definition of “meaningful EHR user” in regulations at § 495.4, one of the requirements of being a meaningful EHR user is to successfully report the clinical quality measures selected by CMS to CMS or a state, as applicable, in the form and manner specified by CMS or the state, as applicable. Section 1848(o)(2)(B)(iii) of the Act requires that in selecting electronic clinical quality measures (eCQMs) for EPs to report under the Promoting Interoperability Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. We have taken steps to align various quality reporting and payment programs that include the submission of eCQMs.

In the “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices” final rule (82 FR 37990, 38487) (hereafter referred to as the “FY 2018 IPPS/LTCH PPS final rule”), we established that, for 2017, Medicaid EPs would be required to report on any six eCQMs that are relevant to the EP’s scope of practice. In proposing and finalizing that change, we indicated that it is our intention to align eCQM requirements for Medicaid EPs with the requirements of Medicare quality improvement programs, to the extent practicable.

2. eCQM Reporting Requirements for EPs Under the Medicaid Promoting Interoperability Program for 2019

CMS annually reviews and revises the list of eCQMs for each MIPS performance year to reflect updated clinical standards and guidelines. In section III.H.3.h.(2)(b)(i) of this proposed rule, we are proposing to amend the list of available eCQMs for the CY 2019 performance period. To keep eCQM specifications current and minimize complexity, we propose to align the eCQMs available for Medicaid EPs in 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period. Specifically, we

propose that the eCQMs available for Medicaid EPs in 2019 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2019 performance period.

We believe that this proposal would be responsive to stakeholder feedback supporting quality measure alignment between MIPS and the Medicaid Promoting Interoperability Program for EPs, and that it would encourage EP participation in the Medicaid Promoting Interoperability Program by allowing those that are also MIPS eligible clinicians the ability to report the same eCQMs as they report for MIPS in 2019. In addition, we believe that aligning the eCQMs available in each program would ensure the most uniform application of up-to-date clinical standards and guidelines possible.

We anticipate that this proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, particularly in light of our belief that many EPs will report eCQMs to meet the quality performance category of MIPS and therefore should be prepared to report on the available eCQMs for 2019. We expect that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2019 to maintain current eCQM lists and specifications.

We also request comments on whether in future years of the Medicaid Promoting Interoperability Program beyond 2019, we should include all e-specified measures from the core set of quality measures for Medicaid and the Children’s Health Insurance Program (CHIP) (the Child Core Set) and the core set of health care quality measures for adults enrolled in Medicaid (Adult Core Set) (hereinafter together referred to as “Core Sets”) as additional options for Medicaid EPs. Sections 1139A and 1139B of the Act require the Secretary to identify and publish core sets of health care quality measures for child Medicaid and CHIP beneficiaries and adult Medicaid beneficiaries. These measure sets are required by statute to be updated annually and are voluntarily reported by states to CMS. These core sets comprise measures that specifically focus on populations served by the Medicaid and CHIP programs and are of particular importance to their care. Several of these Core Set measures are included in the MIPS eCQM list, but some are not. We believe that including as eCQM reporting options for Medicaid

EPs the e-specified measures from the Core Sets that are not also on the MIPS eCQM list would increase EP utilization of these measures and provide states with better data to report. At this time, the only measure within the Core Sets that would not be available as an option for Medicaid EPs in 2019 (because it is not on the MIPS eCQM list) is NQF-1360, “Audiological Diagnosis No Later Than 3 Months of Age.” However, as these Core Sets are updated annually, there may be other eCQMs that could be included in future years.

For 2019, we propose that Medicaid EPs would report on any six eCQMs that are relevant to the EP’s scope of practice, regardless of whether they report via attestation or electronically. After we removed the NQS domain requirements for EPs’ 2017 eCQM submissions in the FY 2018 IPPS/LTCH PPS final rule, we have found that allowing EPs to report on any six quality measures that are relevant to their practice has increased EPs’ flexibility to report pertinent data. In addition, this policy would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established at § 414.1335(a)(1). MIPS eligible clinicians who elect to submit eCQMs must submit data on at least six quality measures, including at least one outcome measure (or, if an applicable outcome measure is not available, one other high priority measure). We refer readers to § 414.1335(a)(2) and (3) for the data submission criteria that apply to individual MIPS eligible clinicians and groups who elect to submit data for other collection types.

We also propose that for 2019 the Medicaid Promoting Interoperability Program would adopt the MIPS requirement that EPs report on at least one outcome measure (or, if an applicable outcome measure is not available or relevant, one other high priority measure). We also request comments on how high priority measures should be identified for Medicaid EPs. We propose to use all three of the following methods to identify which of the available measures are high priority measures, but invite comments on other possibilities.

1. We would use the same set of high priority measures for EPs participating in the Medicaid Promoting Interoperability Program that the MIPS program has identified for eligible clinicians. We note that in section III.H., we are proposing to amend § 414.1305 to revise the definition of high priority measure for purposes of MIPS to mean an outcome (including intermediate-

outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure, beginning with the 2021 MIPS payment year.

2. For 2019, we would also identify as high priority measures the available eCQMs that are included in the previous year’s Core Sets and that are also included on the MIPS list of eCQMs. Because the Core Sets are released at the beginning of each year, it would not be possible to update the list of high-priority eCQMs with those added to the current year’s Core Sets. CMS has already identified the measures included in the Core Sets as ones that specifically focus on populations served by the Medicaid and CHIP programs and are particularly important to their care. The eCQMs that would be available for EPs to report in 2019, that are both part of the Core Sets and on the MIPS list of eCQMs, and that would be considered high priority measures under our proposal are: CMS2, “Preventive Care and Screening: Screening for Depression and Follow-Up Plan”; CMS4, “Initiation and Engagement of Alcohol and Other Drug Dependence Treatment”; CMS122, “Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)”; CMS125, “Breast Cancer Screening”; CMS128, “Anti-depressant Medication Management”; CMS136, “Follow-Up Care for Children Prescribed ADHD Medication (ADD)”; CMS153, “Chlamydia Screening for Women”; CMS155, “Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents”; and CMS165, “Controlling High Blood Pressure.”

3. We would also give each state the flexibility to identify which of the available eCQMs selected by CMS are high priority measures for EPs in that state, with review and approval from CMS, through their State Medicaid HIT Plans (SMHP), similar to the flexibility granted states to modify the definition of Meaningful Use at § 495.332(f). This would give states the ability to identify as high priority those measures that align with their state health goals or other programs within the state. We proposed to amend § 495.332(f) to provide for this state flexibility to identify high priority measures.

We propose that any eCQMs identified via any of these mechanisms be considered to be high priority measures for EPs participating in the Medicaid Promoting Interoperability Program for 2019. We invite comments on whether all three of these methods should be utilized (as proposed) or whether there are reasons to instead use

a subset of these methods, or only one of them.

We also propose that the eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program would be a full CY in 2019 for EPs who have demonstrated meaningful use in a prior year, in order to align with the corresponding performance period in MIPS for the quality performance category. We continue to align Medicaid Promoting Interoperability Program requirements with requirements for other CMS quality programs, such as MIPS, to the extent practicable, to reduce the burden of reporting different data for separate programs. In addition, we have found that clinical quality data from an entire year reporting period is significantly more useful than partial year data for quality measurement and improvement because it gives states a fuller picture of a health care provider’s care and patient outcomes. The eCQM reporting period for EPs demonstrating meaningful use for the first time, which was established in the final rule entitled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017” (80 FR 62762) (hereafter referred to as “Stage 3 final rule”), would remain any continuous 90-day period (80 FR 62892).

We will adjust future years’ requirements for reporting eCQMs in the Medicaid Promoting Interoperability Program as necessary, through rulemaking, and will continue to align the quality reporting requirements, as logical and feasible, to minimize EP burden.

We invite public comment on these proposals.

3. Proposed Revisions to the EHR Reporting Period and eCQM Reporting Period in 2021 for EPs Participating in the Medicaid Promoting Interoperability Program

In the July 28, 2010 final rule titled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program” at 75 FR 44319, we established that, in accordance with section 1903(t)(4)(A)(iii) of the Act, in no case may any Medicaid EP receive an incentive after 2021 (see § 495.310(a)(2)(v)). Therefore, December 31, 2021 is the last date that states could make Medicaid Promoting Interoperability Program payments to Medicaid EPs (other than pursuant to a successful appeal related to 2021 or a prior year).

For states to make payments by that deadline, there must be sufficient time after EHR and eCQM reporting periods

end for EPs to attest to states, for states to conduct their prepayment processes, and for states to issue payments. Therefore, we propose to amend § 495.4 to provide that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program would be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. Similarly, we propose to change the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program to a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021.

We understand that the October 31, 2021 date might not provide some states with sufficient time to process payments by December 31, 2021. We believe that states are best positioned to determine the last possible date in CY 2021 by which the EHR or eCQM reporting periods for Medicaid EPs must end, and the deadline for receiving EP attestations, so that the state is able to issue all payments by December 31, 2021. Therefore, we propose to allow states the flexibility to set alternative, earlier final deadlines for EHR or eCQM reporting periods for Medicaid EPs in CY 2021, with prior approval from us, through their State Medicaid HIT Plan (SMHP). If a state establishes an alternative, earlier date within CY 2021 by which all EHR or eCQM reporting periods in CY 2021 must end, Medicaid EPs in that state would continue to have a reporting period of a minimum of any continuous 90-day period within CY 2021. The end date for the reporting period would have to occur before the day of attestation, which must occur prior to the final deadline for attestations established by their state. We proposed to amend § 495.332(f) to provide for this state flexibility to identify an alternative date by which all EHR reporting periods or eCQM reporting periods for Medicaid EPs in CY 2021 must end.

We believe there is no reason why a state would need to set a date by which EHR reporting periods and eCQM reporting periods must end for Medicaid EPs that is earlier than the day before that state's attestation deadline for EPs. Doing so would restrict EPs' ability to select EHR and eCQM reporting periods. Therefore, we propose that any

alternative deadline for CY 2021 EHR and eCQM reporting periods set by a state may not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state.

We invite public comment on this proposal.

While we are not making any proposals regarding eligible hospitals in this proposed rule, we acknowledge that there will be a similar issue if there are still hospitals eligible to receive Medicaid Promoting Interoperability Program payments in 2021, including Medicaid-only eligible hospitals as well as "dually-eligible" eligible hospitals and critical access hospitals (CAHs) (those that are eligible for an incentive payment under Medicare for meaningful use of CEHRT and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use of CEHRT, and are also eligible to earn a Medicaid incentive payment for meaningful use of CEHRT). However, based on attestation data and information from states' SMHPs regarding the number of years states disburse Medicaid Promoting Interoperability Program payments to hospitals, we believe that there will be no hospitals eligible to receive Medicaid Promoting Interoperability Program payments in 2021 due to the requirement that, after 2016, eligible hospitals cannot receive a Medicaid Promoting Interoperability Program payment unless they have received such a payment in the prior fiscal year. At this time, we believe that there are no hospitals that will be able to receive incentive payments in 2020 or 2021. We invite comments and suggestions on whether this belief is accurate, and if not, how we could address the issue in a manner that limits the burden on hospitals and states. We are not proposing any specific policy in this rule, but, if necessary, we expect to address the issue in a future proposed rule that is more specifically related to hospital payment.

4. Proposed Revisions to Stage 3 Meaningful Use Measures for Medicaid EPs

a. Proposed Change to Objective 6 (Coordination of Care Through Patient Engagement)

In the Stage 3 final rule, we adopted a phased approach under Stage 3 for EP Objective 6 (Coordination of care through patient engagement), Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging). This phased approach established a 5 percent threshold for both measures 1 and 2 of this objective

for an EHR reporting period in 2017. (80 FR 62848 through 62849) In the same rule, we established that the threshold for Measure 1 would rise to 10 percent, beginning with the EHR reporting period in 2018, and that the threshold for Measure 2 would rise to 25 percent, beginning with the EHR reporting period in 2018. We stated that we would continue to monitor performance on these measures to determine if any further adjustment was needed. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38493), we established a policy allowing EPs, eligible hospitals, and CAHs to use either 2014 Edition or 2015 Edition CEHRT, or a combination of 2014 Edition and 2015 Edition CEHRT, for an EHR reporting period in CY 2018, and depending on which Edition(s) they use, to attest to the Modified Stage 2 objectives and measures or the Stage 3 objectives and measures. In doing so, we also delayed the rise of the Objective 6 Measure 1 and Measure 2 thresholds until 2019.

Based on feedback we have received, we understand that these two measures are the largest barrier to successfully demonstrating meaningful use, especially in rural areas and at safety net clinics. Stakeholders have reported a variety of causes that have resulted in lower patient participation than was anticipated when the Stage 3 final rule was issued. The data that we have collected via states for Medicaid EPs and at CMS from Medicare EPs for previous program years supports this feedback. The primary issue is that the view, download, transmit measure requires a positive action by patients, which cannot be controlled by an EP. Medicaid populations that are at the greatest risk have lower levels of internet access, internet literacy and health literacy than the general population. While the Secure Electronic Messaging measure does not require patient action, only that the EP send a secure message, we have received feedback that this functionality is not highly utilized by patients. While we encourage EPs to continue to reach out to patients via secure messaging to engage them in their health care between office visits, it is not productive for EPs to send messages to patients who are unlikely to see them or take action. Retaining the current threshold of 5 percent for both measures would continue to incentivize EPs to engage patients in their own care without raising the requirements to unattainable thresholds for EPs who serve vulnerable Medicaid patients. Therefore, we propose to amend § 495.24(d)(6)(i) such that the thresholds

for Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging) of Meaningful Use Stage 3 EP Objective 6 (Coordination of care through patient engagement) would remain 5 percent for 2019 and subsequent years.

We invite comments on this proposal.

b. Proposed Change to the Syndromic Surveillance Reporting Measure

In the Stage 3 final rule, we established that the syndromic surveillance reporting measure for EPs was limited to those who practice in urgent care settings (80 FR 62866 through 62870). Since then, we have received feedback from states and public health agencies that while many are unable to accept non-emergency or non-urgent care ambulatory syndromic surveillance data electronically, some public health agencies can and do want to receive data from health care providers in non-urgent care settings. We believe that public health agencies that set the requirements for data submission to public health registries are in a better position to judge which health care providers can contribute useful data.

Therefore, we propose to amend § 495.24(d)(8)(i)(B)(2), EP Objective 8 (Public health and clinical data registry reporting), Measure 2 (Syndromic surveillance reporting measure), to amend the language restricting the use of syndromic surveillance reporting for meaningful use only to EPs practicing in an urgent care setting. We propose to include any EP defined by the state or local public health agency as a provider who can submit syndromic surveillance data. This change would not alter the exclusion for this measure at § 495.25(d)(8)(i)(C)(2)(i), for EPs who are not in a category of health care providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system, as defined by the state or local public health agency. Furthermore, this does not create any requirements for syndromic surveillance registries to include all EPs. Additionally, under the specifications for the 2015 Edition of CEHRT for syndromic surveillance, it is possible that an EP could own CEHRT and submit syndromic surveillance in a format that is not accepted by the local jurisdiction. In this case, the EP may take an exclusion for syndromic surveillance.

We invite comments on this proposal.

F. Medicare Shared Savings Program

As required under section 1899 of the Act, we established the Medicare

Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (76 FR 67802) (hereinafter referred to as the "November 2011 final rule"). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (80 FR 32692) (hereinafter referred to as the "June 2015 final rule"). The final rule entitled, "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations," which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the "June 2016 final rule").

We have also made use of the annual calendar year (CY) Physician Fee Schedule (PFS) rules to address quality reporting for the Shared Savings Program and certain other issues. In the CY 2018 PFS final rule (82 FR 53209 through 53226), we finalized revisions to several different policies under the Shared Savings Program, including the assignment methodology, quality measure validation audit process, use of the skilled nursing facility (SNF) 3-day waiver, and handling of demonstration payments for purposes financial reconciliation and establishing historical benchmarks. In addition, in the CY 2017 Quality Payment Program final rule (81 FR 77255 through 77260) and the CY 2018 Quality Payment Program final rule (82 FR 53688 through 53706), we finalized policies related to the Alternative Payment Model (APM) scoring standard under the Merit-Based Incentive Payment System (MIPS), which reduces the reporting burden for MIPS eligible clinicians who participate

in MIPS APMs, such as the Shared Savings Program, by: (1) Using the CAHPS for ACOs survey and the ACO reported CMS Web Interface quality data for purposes of assessing quality performance in the Shared Savings Program and to score the MIPS quality performance category for these eligible clinicians; (2) automatically awarding MIPS eligible clinicians participating in Shared Savings Program ACOs a minimum of one-half of the total points in the MIPS improvement activities performance category; (3) requiring ACO participants to report Advancing Care Information (ACI) data at the group practice level or solo practitioner level; and (4) not assessing MIPS eligible clinicians on the MIPS cost performance category because, through their participation in the ACO, they are already being assessed on cost and utilization under the Shared Savings Program.

As a general summary, we are proposing the following changes to the quality performance measures that will be used to assess quality performance under the Shared Savings Program for performance year 2019 and subsequent years:

- Changes to Patient Experience of Care Survey measures.
- Changes to CMS Web Interface and Claims-Based measures.

1. Quality Measurement

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the November 2011 final rule, we established a quality performance standard consisting of 33 measures across four domains, including patient experience of care, care coordination/patient safety, preventive health, and at-risk population (76 FR 67872 through 67891). Since the Shared Savings Program was established, we have updated the measures that comprise the quality performance standard for the Shared Savings Program through the annual rulemaking in the CY 2015, 2016, and 2017 PFS final rules (79 FR 67907 through 67920, 80 FR 71263 through 71268, and 81 FR 80484 through 80489, respectively).

As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify

measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes.

For performance year 2018, 31 quality measures are used to determine ACO quality performance (81 FR 80488 and 80489). Quality measures are submitted by the ACO through the CMS Web Interface, calculated by CMS from administrative and claims data, and collected via a patient experience of care survey referred to as the Consumer Assessment of Healthcare Provider and Systems (CAHPS) for ACOs Survey. The CAHPS for ACOs survey is based on the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) Survey and includes additional, program specific questions that are not part of the CG-CAHPS. The CG-CAHPS survey is maintained, and periodically updated, by the Agency for Healthcare Research and Quality (AHRQ).

The quality measures collected through the CMS Web Interface in 2015 and 2016 were used to determine whether eligible professionals participating in an ACO would avoid the PQRS and automatic Physician Value-Based Payment Modifier (Value Modifier) downward payment adjustments for 2017 and 2018 and to determine if ACO participants were eligible for upward, neutral or downward adjustments based on quality measure performance under the Value Modifier. Beginning with the 2017 performance period, which impacts payments in 2019, PQRS and the Value Modifier were replaced by the MIPS. Eligible clinicians who are participating in an ACO and subject to MIPS (MIPS eligible clinicians) will be scored under the alternative payment model (APM) scoring standard under MIPS (81 FR 77260). These MIPS eligible clinicians include any eligible clinicians who are participating in an ACO in a track of the Shared Savings Program that is an Advanced APM, but who do not become Qualifying APM Participants (QPs) as specified in § 414.1425, and are not otherwise excluded from MIPS. Beginning with the 2017 reporting period, measures collected through the CMS Web Interface will be used to determine the MIPS quality performance category score for MIPS eligible clinicians participating in a Medicare Shared Savings Program ACO. Starting with the 2018 performance period, the quality performance category under the MIPS APM Scoring Standard for MIPS eligible clinicians participating in a Shared Savings Program ACO will include measures collected through the

CMS Web Interface and the CAHPS for ACOs survey measures.

The CAHPS for ACOs Survey includes the core questions contained in the CG-CAHPS, plus additional questions to measure access to and use of specialist care, experience with care coordination, patient involvement in decision-making, experiences with a health care team, health promotion and patient education, patient functional status, and general health. From 2014 through 2017, ACOs had the option to use a short version of the survey (8 Summary Survey Measures (SSMs) used in assessing quality performance, 1 SSM scored for informational purposes) or a longer version of the survey (8 SSMs used in determining quality performance and 4 SSMs scored for informational purposes). Although not all measures in the longer version of the survey were used in determining the ACO's quality score, the measure performance rate information could be used by the ACO in its quality improvement efforts. For 2018, CMS will only offer one version of the CAHPS for ACOs survey. Eight SSMs will be used in quality determination and two SSMs will be scored for informational purposes. There were no changes to the scored measure set between the 2017 and 2018 surveys: The 2018 survey is a streamlined version of the survey that assesses the same content areas required in 2017, using fewer survey items.

The 2018 CAHPS for ACOs survey incorporates updates made by AHRQ to the Clinician and Group (CG) CAHPS survey that were based on feedback from survey users and stakeholders as well as analyses of multiple data sets. In the "Notice of Proposed Changes for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician & Group Survey" published in the January 21, 2015 **Federal Register** (80 FR 2938–2939), AHRQ solicited public comment on proposed updates to produce the CAHPS Clinician & Group Survey v. 3.0. Based on analyses of multiple data sets and comments received from the public, AHRQ released the CAHPS Clinician & Group Survey v. 3.0. The 2018 CAHPS for ACOs survey includes language refinements and core SSM item changes that align with the CAHPS Clinician & Group Survey v. 3.0.

Additional information on the CG-CAHPS survey update is available on the AHRQ website at <https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/cg/about/proposed-changes-cahps-c&g-survey2015.pdf>.

In addition to incorporating changes based on the AHRQ survey update, CMS removed all items included in the SSMs, *Helping You to Take Medications as Directed* and *Between Visit Communication*. These were optional SSMs that were not part of the scored measures. The update resulted in reducing the number of questions from 80 to 58 questions. Accordingly, the CAHPS for ACOs SSMs that contribute to the ACO performance score for performance year 2018, as finalized in the CY 2017 PFS final rule (81 FR 80488) are: Getting Timely Care, Appointments & Information; How Well Your Providers Communicate; Patients' Rating of Provider; Access to Specialists; Health Promotion and Education; Shared Decision Making; Health Status & Functional Status; and Stewardship of Patient Resources. In addition, the core survey includes SSMs on Care Coordination and Courteous & Helpful Office Staff. However, because these measures are not included in the Shared Savings Program quality measure set for 2018, scores for these measures will be provided to ACOs for informational purposes only and will not be used in determining the ACOs' quality scores.

b. Proposals for Changes to the CAHPS Measure Set

To enhance the Patient/Caregiver Experience domain and align with MIPS (82 FR 54163), we are proposing to begin scoring the 2 SSMs that are currently collected with the administration of the CAHPS for ACOs survey and shared with the ACOs for informational purposes only. Under this proposal, we would add the following CAHPS for ACOs SSMs that are already collected and provided to ACOs for informational purposes to the quality measure set for the Shared Savings Program as ACO-45, CAHPS: Courteous and Helpful Office Staff, and ACO-46: CAHPS: Care Coordination. These measures would be scored and included in the ACO quality determination starting in 2019. Both of these SSMs are currently designated by AHRQ as CG CAHPS core measures.

The Courteous and Helpful Office Staff SSM, which would be added as ACO-45, asks about the helpfulness, courtesy and respectfulness of office staff. This SSM has been a CG-CAHPS core measure in the previous two versions of the CG-CAHPS survey, but was previously provided for informational purposes only and not included in the ACO quality score determination. We are also proposing to add the SSM, CAHPS: Care Coordination to the CAHPS for ACOs

measures used in ACO quality score determination as ACO-46. The Care Coordination SSM asks questions about provider access to beneficiary information and provider follow-up. This SSM was designated a core measure in the most recent version of the CG-CAHPS survey.

Inclusion of these measures in the quality measure set that is used to assess the quality performance of ACOs under the Shared Savings Program would place greater emphasis on outcome measures and the voice of the patient and provide ACOs with an additional incentive to act upon opportunities for improved care coordination and communication, and would align with the MIPS measure set finalized in the CY 2018 Quality Payment Program final rule (82 FR 54163). Care Coordination and patient and caregiver engagement are goals of the Shared Savings Program. The Care Coordination SSM emphasizes the care coordination goal, while the Courteous and Helpful Office Staff SSM supports patient engagement as it addresses a topic that has been identified as important to beneficiaries in testing. For performance year 2016, the mean performance rates across all ACOs for these two measures, which were not included in the ACO quality score determination, were 87.18 for the Care Coordination SSM and 92.12 for Courteous and Helpful Office Staff SSM.

Consistent with § 425.502(a)(4), regarding the scoring of newly introduced quality measures, we propose that these additional SSMs would be pay-for-reporting for all ACOs for 2 years (performance years 2019 and 2020). The measures would then phase into pay-for-performance for ACOs in their first agreement period in the program according to the schedule in Table 25 beginning in performance year 2021. We seek comment on this proposed change to the quality measure set.

Additionally, we seek comment on potentially converting the Health and Functional Status SSM (ACO-7) to pay-for-performance in the future. The Health and Functional Status SSM is currently pay-for-reporting for all years. We have not scored this measure because the scores on the Health and Functional Status SSM may reflect the underlying health of beneficiaries seen by ACO providers/suppliers as opposed to the quality of the care provided by the ACO. We are also considering possible options for enhancing collection of Health and Functional Status data. One option would be to change our data collection procedures to collect data from the same ACO assigned beneficiaries over time. This

change could allow for measurement of changes that occurred while beneficiaries were receiving care from ACO providers/suppliers. We are seeking stakeholder feedback on this approach or other recommendations regarding the potential inclusion of a functional status measure in the assessment of ACO quality performance in the future.

c. Proposed Changes to the CMS Web Interface and Claims-Based Quality Measure Sets

In developing these proposals, we considered the agency's efforts to streamline quality measures, reduce regulatory burden and promote innovation as part of the agency's Meaningful Measures initiative (See CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit, October 30, 2017, available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html>). Under the Meaningful Measures initiative, CMS has committed to assessing only those core issues that are most vital to providing high-quality care and improving patient outcomes, with the aim of focusing on outcome-based measures, reducing unnecessary burden on providers, and putting patients first. In considering the quality reporting requirements under the Shared Savings Program, we have also considered the quality reporting requirements under other initiatives, such as the MIPS and Million Hearts Initiative, and consulted with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date with current clinical guidelines, focus on outcomes over process, reflect agency and program priorities, and reduce reporting burden.

Since the Shared Savings Program was first established in 2012, we have not only updated the quality measure set to reduce reporting burden, but also to focus on more meaningful, outcome-based measures. The most recent updates to the Shared Savings Program quality measure set were made in the CY 2017 PFS final rule (81 FR 80484 through 80489) to adopt the ACO measure recommendations made by the Core Quality Measures Collaborative, a multi-stakeholder group with the goal of aligning quality measures for reporting across public and private initiatives to reduce provider reporting burden. Currently, more than half of the 31 Shared Savings Program quality measures are outcome-based, including:

- Patient-reported outcome measures collected through the CAHPS for ACOs Survey that strengthen patient and caregiver experience.

- Outcome measures supporting effective communication and care coordination, such as unplanned admission and readmission measures.

- Intermediate outcome measures that address the effective treatment of chronic disease, such as hemoglobin A1c control for patients with diabetes.

In this rule, we are proposing to reduce the total number of measures in the Shared Savings Program quality measure set. These proposals are intended to reduce the burden on ACOs and their participating providers and suppliers by lowering the number of measures they are required to report through the CMS Web Interface and on which they are assessed through the use of claims data. Reducing the number of measures on which ACOs are measured would reduce the number of performance metrics that they are required to track and eliminate redundancies between measures that target similar populations. The proposed reduction in the number of measures would enable ACOs to better utilize their resources toward improving patient care. These proposals further reduce burden by aligning with the proposed changes to the CMS Web Interface measures that are reported under MIPS as discussed in Tables A, C, and D of Appendix 1: Proposed MIPS Quality Measures of this proposed rule. We recognize that ACOs and their participating providers and suppliers dedicate resources to performing well on our quality metrics, and we believe that reducing the number of metrics and aligning them across programs would allow them to more effectively target those resources toward improving patient care. We are proposing to reduce the number of measures by minimizing measure overlap and eliminating several process measures. The proposal to remove process measures also aligns with our proposal to reduce the number of process measures within the MIPS measure set as discussed in section III.H.b.iii of this proposed rule and would support the CMS goal of moving toward outcome-based measurement.

We are proposing to retire the following claims-based quality measures, which have a high degree of overlap with other measures that would remain in the measure set:

- ACO-35—Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM).

- ACO-36—All-Cause Unplanned Admissions for Patients with Diabetes.

- ACO-37—All-Cause Unplanned Admission for Patients with Heart Failure.

Within the claims-based quality measures, overlap exists between measures with respect to the population being measured (the denominator), because a single admission may be counted in the numerator for multiple measures. For example, ACO-35 addresses unplanned readmissions from a SNF, and the vast majority of these SNF readmissions are also captured in the numerator of ACO-8 Risk-Standardized All Condition Readmission. Similarly, ACO-36 and ACO-37 address unplanned admissions for patients with diabetes and heart failure and most of these admissions are captured in the numerator of ACO-38 Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions (please note that the measure name has been updated to align with changes made by the measure steward). Therefore, to reduce redundancies within the Shared Savings Program measure set, we propose to remove ACO-35, ACO-36, and ACO-37 from the measure set. However, because these measures are claims-based measures and therefore do not impose any reporting burden on ACOs, we intend to continue to provide information to ACOs on their performance on these measures for use in their quality improvement activities through a new quarterly claims-based quality outcome report that ACOs will begin receiving in 2018.

Although we are proposing to retire ACO-35 (SNFRM) from the set of quality measures that are scored for the Shared Savings Program, we recognize the value of measuring the quality of care furnished to Medicare beneficiaries in SNFs. Therefore, we are seeking comment on the possibility of adding the Skilled Nursing Facility Quality Reporting Program (SNFQRP) measure “Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facilities” to the Shared Savings Program quality measure set through future rulemaking. This measure differs from ACO-35 (Skilled Nursing Facility 30-Day All-Cause Readmission Measure), which we are proposing to remove above, as the SNFQRP measure looks only at unplanned, potentially preventable readmissions for Medicare Fee-For-Service beneficiaries within 30 days of discharge to a lower level of care from a SNF, while ACO-35 assesses

readmissions from a SNF, regardless of cause, that occur within 30 days following discharge from a hospital. As a result, the SNFQRP measure would have less overlap with ACO-8 (Risk-Standardized All Cause Readmission measure) than does ACO-35 (SNFRM), because the two measures’ readmission windows differ. Specifically, the readmission window for the SNFQRP measure is 30 days following discharge from a SNF, while the readmission window for ACO-8 is 30 days following discharge from a hospital.

We are also proposing to retire claims-based measure ACO-44 (Use of Imaging Studies for Low Back Pain), as this measure is restricted to individuals 18–50 years of age, which results in low denominator rates under the Shared Savings Program, meaning that the measure is not a valuable reflection of the beneficiaries cared for by Shared Savings Program ACOs. As a result, although this measure was originally added to the Shared Savings Program quality measure set in order to align with the Core Quality Measures Collaborative, we no longer believe ACO-44 is a meaningful measure that should be retained in the Shared Savings Program quality measure set. The deletion of this measure would also align ACO quality measurement with the MIPS requirements as this measure was removed for purposes of reporting under the MIPS program in the CY 2018 Quality Payment Program final rule (82 FR 54159). However, in recognition of the value in providing feedback to providers on potential overuse of diagnostic procedures, we intend to continue to provide ACOs feedback on performance on this measure as part of the new quarterly claims based quality report.

We welcome public comment on our proposal to retire these 4 claims-based measures from the quality measure set.

Further, we seek to align with changes made to the CMS Web Interface measures under the Quality Payment Program. In the 2017 PFS final rule, we stated we do not believe it is beneficial to propose CMS Web interface measures for ACO quality reporting separately (81 FR 80499). Therefore, in order to avoid confusion and duplicative rulemaking, we adopted a policy that any future changes to the CMS Web interface measures would be proposed and finalized through rulemaking for the Quality Payment Program, and that such changes would be applicable to ACO quality reporting under the Shared

Savings Program. In accordance with the policy adopted in the CY 2017 PFS final rule (81 FR 80501), we are not making any specific proposals related to changes in CMS Web Interface measures reported under the Shared Savings Program. Rather, we refer readers to Tables A, C, and D of Appendix 1: Proposed MIPS Quality Measures of this proposed rule for a complete discussion of the proposed changes to the CMS Web Interface measures. If the proposed changes are finalized, ACOs would no longer be responsible for reporting the following measures for purposes of the Shared Savings Program starting with reporting for performance year 2019:

- ACO-12 (NQF #0097) Medication Reconciliation Post-Discharge.
- ACO-13 (NQF #0101) Falls: Screening for Future Fall Risk.
- ACO-15 (NQF #0043) Pneumonia Vaccination Status for Older Adults.
- ACO-16 (NQF #0421) Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up.
- ACO-41 (NQF #0055) Diabetes: Eye Exam.
- ACO-30 (NQF #0068) Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic.

We note that ACO-41 is one measure within a two-component diabetes composite that is currently scored as one measure. The proposed removal of ACO-41 means that ACO-27 Diabetes Hemoglobin A1c (HbA1c) Poor Control (>9%) would now be assessed as an individual measure. If the proposed changes are finalized as proposed, Table 26 shows the maximum possible points that may be earned by an ACO in each domain and overall in performance year 2019 and in subsequent performance years.

Additionally, we note that we are proposing to add the following measure to the CMS Web Interface for purposes of the Quality Payment Program:

- ACO-47 (NQF #0101) Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls.

If this proposal is finalized, consistent with our policy of adopting changes to the CMS Web Interface Measures through rulemaking for the Quality Payment Program, Shared Savings Program ACOs would be responsible for reporting this measure starting in performance year 2019.

Table 25 shows the proposed Shared Savings Program quality measure set for performance year 2019 and subsequent performance years.

TABLE 25—PROPOSED MEASURE SET FOR USE IN ESTABLISHING THE SHARED SAVINGS PROGRAM QUALITY PERFORMANCE STANDARD, STARTING WITH PERFORMANCE YEAR 2019

Domain	ACO measure No.	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase-in R—Reporting P—Performance		
						PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience. <								

¹ Measures that are currently collected as part of the administration of the CAHPS for ACO survey, but will be considered new measures for purposes of the pay for performance phase-in.

² The language in parentheses has been added for clarity and no changes have been made to the measure.

We are proposing to eliminate 10 measures and to add one measure to the Shared Savings Program quality measure set. This would result in 24 measures for which ACOs would be held accountable. With these proposed measure changes, the 4 domains would

include the following numbers of quality measures (See Table 26):

- Patient/Caregiver Experience of Care—10 measures.
- Care Coordination/Patient Safety—5 measures, including the double-weighted EHR measure (ACO-11).
- Preventive Health—6 measures.

- At Risk Populations—3 measures.

Table 26 provides a summary of the number of measures by domain and the total points and domain weights that would be used for scoring purposes under the changes to the quality measure set proposed in this proposed rule.

TABLE 26—NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE SHARED SAVINGS PROGRAM QUALITY PERFORMANCE STANDARD, STARTING WITH PERFORMANCE YEAR 2019

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (%)
Patient/Caregiver Experience	10	10 individual survey module measures	20	25
Care Coordination/Patient Safety	5	5 measures, including double-weighted EHR measure.	12	25
Preventive Health	6	6 measures	12	25
At-Risk Population	3	3 individual measures	6	25
Total in all Domains	24	24	50	100

G. Physician Self-Referral Law

1. Background

Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. Additionally, the statute mandates refunding any amount collected under a bill for an item or service furnished under a prohibited referral. Finally, the statute imposes reporting requirements and provides for sanctions, including civil monetary penalty provisions.

Section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) added provisions to section 1877(h)(1) of the Act pertaining to the writing and signature requirements in certain compensation arrangement exceptions to the statute's referral and billing prohibitions. Although we believe that the newly enacted provisions in section 1877(h)(1) of the Act are principally intended merely to codify in statute existing CMS policy and regulations with respect to compliance with the writing and signature requirements, we are proposing revisions to our regulations to address any actual or perceived difference between the statutory and regulatory language, to codify in regulation our longstanding policy regarding satisfaction of the writing requirement found in many of the exceptions to the physician self-referral law, and to make the Bipartisan Budget Act of 2018 policies applicable

to compensation arrangement exceptions issued using the Secretary's authority in section 1877(b)(4) of the Act.

In the CY 2016 PFS final rule with comment period (80 FR 70885), we revised § 411.357(a)(7), (b)(6), and (d)(1)(vii) to permit a lease arrangement or personal service arrangement to continue indefinitely beyond the stated expiration of the written documentation describing the arrangement under certain circumstances. Section 50404 of the Bipartisan Budget Act of 2018 added substantively identical holdover provisions to section 1877(e) of the Act. Because the new statutory holdover provisions effectively mirror the existing regulatory provisions, we do not believe it is necessary to revise § 411.357(a)(7), (b)(6), and (d)(1)(vii) as a result of these statutory revisions.

2. Special Rules on Compensation Arrangements (Section 1877(h)(1)(E) of the Act)

Many of the exceptions for compensation arrangements in § 411.357 require that the arrangements are set out in writing and signed by the parties. (See § 411.357(a)(1), (b)(1), (d)(1)(i), (e)(1)(i), (e)(4)(i), (l)(1), (p)(2), (q) (incorporating the requirement contained in § 1001.952(f)(4)), (r)(2)(ii), (t)(1)(ii) or (t)(2)(iii) (both incorporating the requirements contained in § 411.357(e)(1)(i)), (v)(7), (w)(7), (x)(1)(i), and (y)(1).)⁷ As described above, section 50404 of the Bipartisan Budget Act of 2018 amended section 1877 of the Act with respect to the writing and signature requirements in the statutory compensation arrangement exceptions. As detailed below, we are proposing a new special rule on compensation arrangements at § 411.354(e) and

proposing to amend existing § 411.353(g) to codify the statutory provisions in our regulations.

a. Writing Requirement (§ 411.354(e))

In the CY 2016 PFS final rule with comment period, we stated CMS' longstanding policy that the writing requirement in various compensation arrangement exceptions in § 411.357 can be satisfied by “a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties” (80 FR 71315). Our guidance on the writing requirement appeared in the preamble of the CY 2016 PFS final rule with comment period but was not codified in regulations. Section 50404 of the Bipartisan Budget Act of 2018 added subparagraph D, “Written Requirement Clarified,” to section 1877(h)(1) of the Act. Section 1877(h)(1)(D) of the Act provides that, in the case of any requirement in section 1877 of the Act for a compensation arrangement to be in writing, such requirement shall be satisfied by such means as determined by the Secretary, including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties involved.

In light of the recently added statutory provision at section 1877(h)(1)(D) of the Act, we are proposing to add a special rule on compensation arrangements at § 411.354(e). Proposed § 411.354(e) provides that, in the case of any requirement in 42 CFR part 411, subpart J, for a compensation arrangement to be in writing, the writing requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. The special rule at § 411.357(e) codifies our existing policy on the writing requirement, as previously articulated in the CY 2016 PFS final rule with comment period. (See 80 FR 71314 *et seq.*)

⁷ We note that, where the writing requirement appears in the statutory and regulatory exceptions, we interpret it uniformly, regardless of any minor differences in the language of the requirement. See 80 FR 71315. Similarly, we interpret the signature requirement uniformly where it appears, regardless of any minor differences in the language of the statutory and regulatory exceptions.

b. Special Rule for Certain Arrangements Involving Temporary Noncompliance With Signature Requirements (§ 411.353(g))

Many of the exceptions for compensation arrangements in § 411.357 require that the arrangement (that is, the written documentation evidencing the arrangement) is signed by the parties to the arrangement. Under our existing special rule for certain arrangements involving temporary noncompliance with signature requirements at § 411.353(g)(1), an entity that has a compensation arrangement with a physician that satisfies all the requirements of an applicable exception in § 411.355, § 411.356 or § 411.357 except the signature requirement may submit a claim and receive payment for a designated health service referred by the physician, provided that: (1) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant (without regard to whether any referrals occur or compensation is paid during such 90-day period); and (2) the compensation arrangement otherwise complies with all criteria of the applicable exception. Existing § 411.353(g)(1) specifies the paragraphs where the applicable signature requirements are found and existing § 411.353(g)(2) limits an entity's use of the special rule at § 411.353(g)(1) to only once every 3 years with respect to the same referring physician.

Section 50404 of the Bipartisan Budget Act of 2018 added subparagraph E, "Signature Requirement," to section 1877(h)(1) of the Act. Section 1877(h)(1)(E) of the Act provides that, in the case of any requirement in section 1877 of the Act for a compensation arrangement to be in writing and signed by the parties, the signature requirement is satisfied if: (1) Not later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant, the parties obtain the required signatures; and (2) the compensation arrangement otherwise complies with all criteria of the applicable exception. Notably, under the newly added section 1877(h)(1)(E) of the Act, an applicable signature requirement is not limited to specific exceptions and entities are not limited in their use of the rule to only once every 3 years with respect to the same referring physician. In addition, section 1877(h)(1)(E) of the Act does not include a reference to the occurrence of referrals or the payment of

compensation during the 90-day period when the signature requirement is not met.

To conform the regulations with the recently added statutory provision at section 1877(h)(1)(E) of the Act, we are proposing to amend existing § 411.353(g) by: (1) Revising the reference at § 411.353(g)(1) to specific exceptions and signature requirements; (2) deleting the reference at § 411.353(g)(1) to the occurrence of referrals or the payment of compensation during the 90-day period when the signature requirement is not met; and (3) deleting the limitation at § 411.353(g)(2). In the alternative, we are proposing to delete § 411.353(g) in its entirety and codify in proposed § 411.354(e) the special rule for signature requirements in section 1877(h)(1)(E). We seek comments regarding the best approach for codifying in regulation this provision of the Bipartisan Budget Act of 2018.

Finally, we note that the effective date of section 50404 of the Bipartisan Budget Act was February 9, 2018. Thus, beginning February 9, 2018, parties who meet the requirements of section 1877(h)(1)(E) of the Act, including parties who otherwise would have been barred from relying on the special rule for certain arrangements involving temporary noncompliance with signature requirements at § 411.353(g)(1) because of the 3-year limitation at § 411.353(g)(2), may avail themselves of the new statutory provision at section 1877(h)(1)(E) of the Act.

H. CY 2019 Updates to the Quality Payment Program

1. Executive Summary

a. Overview

This proposed rule would make payment and policy changes to the Quality Payment Program. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015) amended title XVIII of the Act to repeal the Medicare sustainable growth rate (SGR) formula, to reauthorize the Children's Health Insurance Program, and to strengthen Medicare access by improving physician and other clinician payments and making other improvements. The MACRA advances a forward-looking, coordinated framework for clinicians to successfully take part in the Quality Payment Program that rewards value in one of two ways:

- The Merit-based Incentive Payment System (MIPS).
- Advanced Alternative Payment Models (Advanced APMs).

As we move into the third year of the Quality Payment Program, we have taken all stakeholder input into consideration including recommendations made by the Medicare Payment Advisory Commission (MedPAC), an independent congressional agency established by the Balanced Budget Act of 1997 (Pub. L. 105–33) to advise the U.S. Congress on issues affecting the Medicare program, including payment policies under Medicare, the factors affecting expenditures for the efficient provision of services, and the relationship of payment policies to access and quality of care for Medicare beneficiaries. We will continue to implement the Quality Payment Program as required, smoothing the transition where possible and offering targeted educational resources for program participants. A few examples of how we are working to address MedPAC's concerns are evident in our work around burden reduction and reshaping our focus of interoperability. Additionally, we heard the concern about process-based measures, and we are continuing to move towards the development and use of more outcome measures by way of removing process measures that are topped out and funding new quality measure development, as required by section 102 of MACRA. Additionally, we are also developing new episode-based cost measures, with stakeholder feedback, for potential inclusion in the cost performance category beginning in 2019. CMS acknowledges that the Quality Payment Program is a large shift for many clinicians and practices, and thus, we will continue to implement the program gradually with targeted educational resources, public trainings, and technical assistance for those who qualify. With MIPS, eligible clinicians now report under one program, which replaces three separate legacy programs. The Quality Payment Program takes a comprehensive approach to payment. Instead of basing payment only on a series of fee-for-service billing codes, the Quality Payment Program adds consideration of quality through a set of evidence-based measures and clinical practice improvement activities that were primarily developed by clinicians.

As a priority for Quality Payment Program Year 3, we are committed to reducing clinician burden, implementing the Meaningful Measures Initiative, promoting interoperability, continuing our support of small and rural practices, empowering patients through the Patients Over Paperwork initiative, and promoting price transparency.

Reducing Clinician Burden

We are committed to reducing clinician burden by simplifying and reducing burden for participating clinicians. Examples include:

- Implementing the Meaningful Measures Initiative, which is a framework that applies a series of cross-cutting criteria to keep the most meaningful measures with the least amount of burden and greatest impact on patient outcomes;

- Promoting advances in interoperability; and
- Establishing an automatic extreme and uncontrollable circumstances policy for MIPS eligible clinicians.

Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for us. To reduce the regulatory burden on the healthcare industry, lower health

care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.⁸ This initiative is one component of our agency-wide Patients Over Paperwork Initiative,⁹ which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that fosters operational efficiencies and will reduce costs, including the collection and reporting burden, while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures Framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures);
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

To achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in Table 27.

TABLE 27—MEANINGFUL MEASURES FRAMEWORK DOMAINS AND MEASURE AREAS

Quality priority	Meaningful measure area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections.
Strengthen Person and Family Engagement as Partners in Their Care	Preventable Healthcare Harm.
	Care is Personalized and Aligned with Patient's Goals.
	End of Life Care according to Preferences.
	Patient's Experience of Care.
Promote Effective Communication and Coordination of Care	Patient Reported Functional Outcomes.
	Medication Management.
	Admissions and Readmissions to Hospitals.
Promote Effective Prevention and Treatment of Chronic Disease	Transfer of Health Information and Interoperability.
	Preventive Care.
	Management of Chronic Conditions.
	Prevention, Treatment, and Management of Mental Health.
	Prevention and Treatment of Opioid and Substance Use Disorders.
Work with Communities to Promote Best Practices of Healthy Living	Risk Adjusted Mortality.
	Equity of Care.
Make Care Affordable	Community Engagement.
	Appropriate Use of Healthcare.
	Patient-focused Episode of Care.
	Risk Adjusted Total Cost of Care.

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families,

and health care providers while reducing burden and costs for clinicians and providers and promoting operational efficiencies.

In the quality performance category, clinicians have the flexibility to select and report the measures that matter most to their practice and patients. However, we have received feedback that some clinicians find the performance requirements confusing, and the program makes it difficult for them to choose measures that are meaningful to their practices and have more direct benefit to beneficiaries. For

the 2019 MIPS performance period, we are proposing the following updates: (1) Adding 10 new MIPS quality measures that include 4 patient reported outcome measures, 7 high priority measures, 1 measure that replaces an existing measure, and 2 other measures on important clinical topics in the Meaningful Measures framework; and (2) removing 34 quality measures.

In addition to having the right measures, we want to ensure that the collection of information is valuable to clinicians and worth the cost and burden of collecting the information. In

⁸ Meaningful Measures web page: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

⁹ See Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017, <https://www.cms.gov/>

[Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html](https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html).

section III.H.3.h.(2)(b)(iv) of this proposed rule, we are requesting comments on a tiered scoring system for quality measures where measures would be awarded points based on their value. We are also seeking comment on what patient reported outcome measures produce better outcomes and request accompanying supporting evidence that the measures do, in fact, improve outcomes.

Promoting Interoperability Performance Category

As required by MACRA, the Quality Payment Program includes a MIPS performance category that focuses on meaningful use of certified EHR technology, referred to in the CY 2017 and CY 2018 Quality Payment Program rules as the “advancing care information” performance category. As part of our approach to promoting and prioritizing interoperability of healthcare data, in Quality Payment Program Year 2, we changed the name of the performance category to the Promoting Interoperability performance category.

We have prioritized interoperability, which we define as health information technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable law; and does not constitute information blocking as defined by the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016). We are committed to working with the Office of the National Coordinator for Health IT (ONC) on implementation of the interoperability provisions of the 21st Century Cures Act to have seamless but secure exchange of health information for clinicians and patients, ultimately enabling Medicare beneficiaries to get their claims information electronically. In addition, we are prioritizing quality measures and improvement activities that lead to interoperability.

To further CMS’ commitment to implementing interoperability, at the 2018 Healthcare Information and Management Systems Society (HIMSS) conference, CMS Administrator Seema Verma announced the launching of the MyHealthEData initiative.¹⁰ This initiative aims to empower patients by

ensuring that they control their healthcare data and can decide how their data is going to be used, all while keeping that information safe and secure. The overall government-wide initiative is led by the White House Office of American Innovation with participation from HHS—including its CMS, ONC, and the National Institutes of Health (NIH)—as well as the U.S. Department of Veterans Affairs (VA). MyHealthEData aims to break down the barriers that prevent patients from having electronic access and true control of their own health records from the device or application of their choice. This effort will approach the issue of healthcare data from the patient’s perspective.

For the Promoting Interoperability performance category, we require MIPS eligible clinicians to use 2015 Edition certified EHR technology beginning with the 2019 MIPS performance period to make it easier for:

- Patients to access their data.
- Patient information to be shared between doctors and other health care providers.

Continuing To Support Small and Rural Practices

We understand that the Quality Payment Program is a big change for clinicians, especially for those in small and rural practices. We intend to continue to offer tailored flexibilities to help these clinicians to participate in the program. For example, we propose to retain a small practice bonus under MIPS by moving it to the quality performance category. We will also continue to support small and rural practices by offering free and customized resources available within local communities, including direct, one-on-one support from the Small, Underserved, and Rural Support Initiative along with our other no-cost technical assistance.

Further, we note that we are proposing to amend our regulatory text to allow small practices to continue using the Medicare Part B claims collection type. We are also proposing to revise the regulatory text to allow a small practice to submit quality data for covered professional services through the Medicare Part B claims submission type for the quality performance category, as discussed further in section III.H.3.h. of this proposed rule. Finally, small practices may continue to choose to participate in MIPS as a virtual group, as discussed in section III.H.3. of this proposed rule.

Empowering Patients Through the Patients Over Paperwork Initiative

Our Patients Over Paperwork initiative establishes an internal process to evaluate and streamline regulations with a goal to reduce unnecessary burden, to increase efficiencies, and to improve the beneficiary experience.¹¹ This administration is dedicated to putting patients first, empowering consumers of healthcare to have the information they need to be engaged and active decision-makers in their care. As a result of this consumer empowerment, clinicians will gain competitive advantage by delivering coordinated, high-value quality care.

The proposals for the Quality Payment Program in this proposed rule seek to promote competition and to empower patients. We are consistently listening, and we are committed to using data-driven insights, increasingly aligned and meaningful quality measures, and technology that empowers patients and clinicians to make decisions about their healthcare.

In conjunction with development of the Patients Over Paperwork initiative, we are making progress toward developing a patient-centered portfolio of measures for the Quality Payment Program, including 7 new outcome measures included on the 2017 CMS Measures Under Consideration List,¹² 5 of which are directly applicable to the prioritized specialties of general medicine/crosscutting and orthopedic surgery. Finally, on March 2, 2018, CMS announced a funding opportunity for \$30 million in grants to be awarded for quality measure development. The funding opportunity is aimed at external stakeholders with insight into clinician and patient perspectives on quality measurement and areas for improvement to advance quality measures for the Quality Payment Program.¹³

¹¹ Patients Over Paperwork web page available at <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/PatientsOverPaperwork.html>.

¹² Centers for Medicare & Medicaid Services. *List of Measures Under Consideration for December 1, 2017*. Baltimore, MD: US Department of Health and Human Services; 2017. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-Listfor2017.pdf>. Accessed May 4, 2018.

¹³ Centers for Medicare & Medicaid Services. Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Funding Opportunity: Measure Development for the Quality Payment Program. Baltimore, MD: US Department of Health and Human Services; 2018. <https://blog.cms.gov/2018/03/02/medicare-access-and-chipreauthorization-act-of-2015-macra-funding-opportunity/>. Accessed May 4, 2018.

¹⁰ <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-03-06.html>.

Promoting Price Transparency

Through the Executive Order Promoting Healthcare Choice and Competition Across the United States (E.O. 13813, 82 FR 48385 (Oct. 12, 2017)), the President prioritized changing the rate of growth of healthcare spending to foster competition in healthcare markets, resulting in the American people receiving better value for their investment in healthcare. To support these goals, we are helping patients control their health data and make it easier to take their data with them as they move in and out of the healthcare system. This will let patients make informed choices about their care, leading to more competition and lower costs.

b. Summary of the Major Provisions

(1) Quality Payment Program Year 3

We believe the third year of the Quality Payment Program should build upon the foundation that has been established in the first 2 years, which provides a trajectory for clinicians moving to a performance-based payment system. This trajectory provides clinicians the ability to participate in the program through two pathways: MIPS and Advanced APMs.

(2) Payment Adjustments

As discussed in section VII.F.8. of this proposed rule, for the 2021 MIPS payment year and based on Advanced APM participation during the 2019 MIPS performance period, we estimate that between 160,000 and 215,000 clinicians will become Qualifying APM Participants (QP). As a QP, an eligible clinician is exempt from the MIPS reporting requirements and payment adjustment, and qualifies for a lump sum incentive payment based on 5 percent of their aggregate payment amounts for covered professional services for the prior year. We estimate that the total lump sum APM incentive payments will be approximately \$600–800 million for the 2021 Quality Payment Program payment year.

For MIPS, we have posted a blog that provides preliminary participation information for the first year of MIPS.¹⁴ However, due to time constraints, we are unable to incorporate and analyze the performance and participation data from the first year of MIPS for the estimates in this proposed rule. Therefore, under the policies proposed in this proposed rule, we based our estimates for the 2019 MIPS

performance period/2021 MIPS payment year on historical 2016 PQRS and Medicare and Medicaid EHR Incentive Program data. We estimate that approximately 650,000 clinicians would be MIPS eligible clinicians in the 2019 MIPS performance period. This number will depend on a number of factors, including the number of eligible clinicians excluded from MIPS based on their status as QPs or Partial QPs, the number that report as groups, and the number that elect to opt-in to MIPS. In the 2021 MIPS payment year, MIPS payment adjustments, which only apply to covered professional services, will be applied based on MIPS eligible clinicians' performance on specified measures and activities within four integrated performance categories. We estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments (\$372 million) and positive MIPS payment adjustments (\$372 million) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Positive MIPS payment adjustments will also include up to an additional \$500 million for exceptional performance to MIPS eligible clinicians whose final score meets or exceeds the proposed additional performance threshold of 80 points. However, the distribution will change based on the final population of MIPS eligible clinicians for the 2021 MIPS payment year and the distribution of final scores under the program. We anticipate that we will be able to update these estimates with the data from the first year of MIPS in the CY 2019 Quality Payment Program final rule.

2. Definitions

At § 414.1305, subpart O—

- We define the following terms:
 - ++ Ambulatory Surgical Center (ASC)-based MIPS eligible clinician.
 - ++ Collection type.
 - ++ Health IT vendor.
 - ++ MIPS determination period.
 - ++ Submission type.
 - ++ Submitter type.
 - ++ Third party intermediary.
- We revise the definitions of the following terms:
 - ++ High priority measure.
 - ++ Hospital-based MIPS eligible clinician
 - ++ Low-volume threshold.
 - ++ MIPS eligible clinician.
 - ++ Non-patient facing MIPS eligible clinician.
 - ++ Qualified Clinical Data Registry (QCDR).
 - ++ Qualifying APM Participant (QP).
 - ++ Small practices.

These terms and definitions are discussed in detail in relevant sections of this proposed rule.

3. MIPS Program Details

a. MIPS Eligible Clinicians

Under § 414.1305, a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, is defined as any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); and a group that includes such clinicians. Section 1848(q)(1)(C)(II) of the Act provides the Secretary with discretion, beginning with the 2021 MIPS payment year, to specify additional eligible clinicians (as defined in section 1848(k)(3)(B) of the Act) as MIPS eligible clinicians. Such clinicians may include physical therapists, occupational therapists, or qualified speech-language pathologists; qualified audiologists (as defined in section 1861(ll)(3)(B) of the Act); certified nurse-midwives (as defined in section 1861(gg)(2) of the Act); clinical social workers (as defined in section 1861(hh)(1) of the Act); clinical psychologists (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietitians or nutrition professionals.

We received feedback from non-physician associations representing each type of additional eligible clinician through listening sessions and meetings with various stakeholder entities and through public comments discussed in the CY 2017 Quality Payment Program final rule (81 FR 77038). Commenters generally supported the specification of such clinicians as MIPS eligible clinicians beginning with the 2021 MIPS payment year.

To assess whether these additional eligible clinicians could successfully participate in MIPS, we evaluated whether there would be sufficient measures and activities applicable and available for each of the additional eligible clinician types. We focused our analysis on the quality and improvement activities performance categories because these performance categories require submission of data. We did not focus on the Promoting Interoperability performance category because there is extensive analysis regarding who can participate under the current exclusion criteria. In addition,

¹⁴ <https://blog.cms.gov/2018/05/31/quality-payment-program-exceeds-year-1-participation-goal/>.

in section III.H.3.i.(2)(b) of this proposed rule, we are proposing to automatically assign a zero percent weighting for the Promoting Interoperability performance category for these new types of MIPS eligible clinicians. In addition, we did not focus on the cost performance category because we are only able to assess cost performance for a subset of eligible clinicians—those who are currently eligible as a result of not meeting any of the current exclusion criteria. So the impact of the cost performance category for these additional eligible clinicians will continue to be considered but is currently not a decisive factor. From our analysis, we found that improvement activities would generally be applicable and available for each of the additional eligible clinician types. However, for the quality performance category, we found that not all of the additional eligible clinician types would have sufficient MIPS quality measures applicable and available. As discussed in section III.H.3.h.(2)(b)(iii) of this proposed rule, for the quality performance category, we are proposing to remove several MIPS quality measures. If those measures are finalized for removal, we anticipate that qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals would each have less than 6 MIPS quality measures applicable and available to them. However, if the quality measures are not finalized for removal, we will reassess whether these eligible clinicians would have an adequate amount of MIPS quality measures available to them. If we find that these additional clinicians do have at least 6 MIPS quality measures available to them, then we propose to include them in the MIPS eligible clinician definition. We are focusing on the quality performance category because as discussed above, the quality and improvement activities performance categories require submission of data. We believe there would generally be applicable and available improvement activities for each of the additional eligible clinician types, but that not all of the additional eligible clinician types would have sufficient MIPS quality measures applicable and available if the proposed MIPS quality measures are removed from the program. We did find QCDR measures approved for the CY 2018 performance period that are either high priority and/or outcome measures that, if approved for the CY 2019 performance period, may be applicable to these additional eligible clinicians. However, this would necessitate that

they utilize a QCDR in order to be successful in MIPS.

Further, we have heard some concerns from the non-physician associations, through written correspondence, that since their clinicians would be joining the program 2 years after its inception, we should consider several ramp-up policies in order to facilitate an efficient integration of these clinicians into MIPS. We note that the MIPS program is still ramping up, and we will continue to increase the performance threshold to ensure a gradual and incremental transition to the performance threshold until Quality Payment Program Year 6. Therefore, if specified as MIPS eligible clinicians beginning with the 2021 MIPS payment year, the additional eligible clinicians would have 4 years in the program in order to ramp up. Conversely, if specified as MIPS eligible clinicians beginning in a future year, they would be afforded less time to ramp up the closer the program gets to Quality Payment Program Year 6.

Therefore, we request comments on our proposal to amend § 414.1305 to modify the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to mean any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, clinical social worker (as defined in section 1861(hh)(1) of the Act), and clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and a group that includes such clinicians. Alternatively, we propose that if the quality measures proposed for removal are not finalized, then we would include additional eligible clinician types in the definition of a MIPS eligible clinician beginning with the 2021 MIPS payment year (specifically, qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals), provided that we determine that each applicable eligible clinician type would have at least 6 MIPS quality measures available to them. In addition, we are requesting comments on: (1) Specifying qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or

nutrition professionals as MIPS eligible clinicians beginning with the 2021 MIPS payment year; and (2) delaying the specification of one or more additional eligible clinician types as MIPS eligible clinicians until a future MIPS payment year.

b. MIPS Determination Period

Currently, MIPS uses various determination periods to identify certain MIPS eligible clinicians for consideration for certain applicable policies. For example, the low-volume threshold, non-patient facing, small practice, hospital-based, and ambulatory surgical center (ASC)-based determinations are on the same timeline with slight differences in the claims run-out policies, whereas the facility-based determinations has a slightly different determination period. The virtual group eligibility determination requires a separate election process. We are proposing in this rule to add a virtual group eligibility determination period beginning in CY 2020 as discussed in section III.H.3.f.(2)(a) of this proposed rule. In addition, the rural and health professional shortage area (HPSA) determinations do not utilize a determination period.

Under § 414.1305, the low-volume threshold determination period is described as a 24-month assessment period consisting of an initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period, and a second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2020 MIPS payment year and future years, each segment of the low-volume threshold determination period includes a 30-day claims run out.

Under § 414.1305, the non-patient facing determination period is described as a 24-month assessment period consisting of an initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period and a second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance

period through the first 8 months of the calendar year performance period. An individual eligible MIPS clinician, group, or virtual group that is identified as non-patient facing during the initial 12-month segment will continue to be considered non-patient facing for the applicable year regardless of the results of the second 12-month segment analysis. For the 2020 MIPS payment year and future years, each segment of the non-patient facing determination period includes a 30-day claims run out.

In the CY 2018 Quality Payment Program final rule (82 FR 53581), we finalized that for the small practice size determination period, we would utilize a 12-month assessment period, which consists of an analysis of claims data that spans from the last 4 months of a calendar year 2 years prior to the performance period followed by the first 8 months of the next calendar year and includes a 30-day claims run out.

In the CY 2017 Quality Payment Program final rule (81 FR 77238 through 77240), we finalized that to identify a MIPS eligible clinician as hospital-based we would use claims with dates of service between September 1 of the calendar year 2 years preceding the performance period through August 31 of the calendar year preceding the performance period, but in the event it is not operationally feasible to use claims from this time period, we would use a 12-month period as close as practicable to this time period.

In the CY 2018 Quality Payment Program final rule (82 FR 53684 through 53685), we finalized that to identify a MIPS eligible clinician as ASC-based, we would use claims with dates of service between September 1 of the calendar year 2 years preceding the performance period through August 31 of the calendar year preceding the performance period, but in the event it is not operationally feasible to use claims from this time period, we would use a 12-month period as close as practicable to this time period.

In the CY 2018 Quality Payment Program final rule (82 FR 53760), we discussed, but did not finalize, our proposal or the alternative option for how an individual clinician or group would elect to use and be identified as using facility-based measurement for the MIPS program. Because we were not offering facility-based measurement until the 2019 MIPS performance period, we did not need to finalize either of these for the 2018 MIPS performance period. However, in section III.H.3.i.(1)(d) of this proposed rule, we are proposing to amend § 414.1380(e)(2)(i)(A) to specify a criterion for a clinician to be eligible for

facility-based measurement. Specifically, that is, the clinician furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting based on claims for a 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period with a 30-days claims run out. We are not proposing to utilize the MIPS determination period for purposes of the facility-based determination because for the facility-based determination, we are only using the first segment of the MIPS determination period. We are using the first segment because the performance period for measures in the hospital value-based purchasing program overlapped in part with that determination period. If we were to use the second segment, we could not be assured that the clinician actually worked in the hospital on which their MIPS score would be based during that time. We believe this approach provides clarity and is a cleaner than providing a special exception for the facility-based determination in the MIPS determination period for the second segment. We refer readers to section III.H.3.i.(1)(d) for further details on the facility-based determinations and the time periods that are applicable to those determinations.

In the CY 2018 Quality Payment Program final rule (82 FR 53602 through 53604), we finalized that for the virtual group eligibility determination period, we would utilize an analysis of claims data during an assessment period of up to 5 months that would begin on July 1 and end as late as November 30 of the calendar year prior to the applicable performance period and include a 30-day claims run out. To capture a real-time representation of TIN size, we finalized that we would analyze up to 5 months of claims data on a rolling basis, in which virtual group eligibility determinations for each TIN would be updated and made available monthly. We noted that an eligibility determination regarding TIN size is based on a relative point in time within the 5-month virtual group eligibility determination period, and not made at the end of such 5-month determination period. Beginning with the 2019 performance period, we are proposing to amend § 414.1315(c)(1) to establish a

virtual group eligibility determination period to align with the first segment of the MIPS determination period, which includes an analysis of claims data during a 12-month assessment period (fiscal year) that would begin on October 1 of the calendar year 2 years prior to the applicable performance period and end on September 30 of the calendar year preceding the applicable performance period and include a 30-day claims run out. We refer readers to section III.H.3.f.(2)(a) for further details on this proposal.

In addition, we have established other special status determinations, including rural area and HPSA. Rural area is defined at § 414.1305 as a ZIP code designated as rural, using the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available. HPSAs are defined at § 414.1305 as areas designated under section 332(a)(1)(A) of the Public Health Service Act.

We understand that the current use of various MIPS determination periods is complex and causes confusion. Therefore, beginning with the 2021 MIPS payment year, we propose to consolidate several of these policies into a single MIPS determination period that would be used for purposes of the low-volume threshold and to identify MIPS eligible clinicians as non-patient facing, a small practice, hospital-based, and ASC-based, as applicable. We are not proposing to include the facility-based or virtual group eligibility determination periods or the rural and HPSA determinations in the MIPS determination period, as they each require a different process or timeline that does not align with the other determination periods, or do not utilize determination periods. We invite public comments on the possibility of incorporating these determinations into the MIPS determination period in the future.

There are several reasons we believe a single MIPS determination period for most of the eligibility criteria is the most appropriate. First, it would simplify the program by aligning most of the MIPS eligibility determination periods. Second, it would continue to allow us to provide eligibility determinations as close to the beginning of the performance period as feasible. Third, we believe a timeframe that aligns with the fiscal year is easier to communicate and more straightforward to understand compared to the current determination periods. Finally, it would allow us to extend our data analysis an additional 30 days.

It is important to note that during the final 3 months of the calendar year in

which the performance period occurs, in general, we do not believe it would be feasible for many MIPS eligible clinicians who join an existing practice (existing TIN) or join a newly formed practice (new TIN) to participate in MIPS as individuals. We refer readers to section III.H.3.i.(2)(b) of this proposed rule for more information on the proposed reweighting policies for MIPS eligible clinicians who join an existing practice or who join a newly formed practice during this timeframe.

We request comments on our proposal that beginning with the 2021 MIPS payment year, the MIPS determination period would be a 24-month assessment period including a two-segment analysis of claims data consisting of: (1) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period; and (2) a second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs. The first segment would include a 30-day claims run out. The second segment would not include a claims run out, but would include quarterly snapshots for informational use only, if technically feasible. For example, a clinician could use the quarterly snapshots to understand their eligibility status between segments. Specifically, we believe the quarterly snapshots would be helpful for new TIN/NPIs and TINs created between the first segment and the second segment allowing them to see their preliminary eligibility status sooner. Without the quarterly snapshots, these clinicians would not have any indication of their eligibility status until just before the submission period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold, or a MIPS eligible clinician that is identified as non-patient facing, a small practice, hospital-based, or ASC-based, as applicable, during the first segment would continue to be identified as such for the applicable MIPS payment year regardless of the second segment. For example, for the 2021 MIPS payment year, the first segment would be October 1, 2017 through September 30, 2018, and the second segment would be October 1, 2018 through September 30, 2019. However, based on our experience with the Quality Payment Program, we believe that some eligible clinicians, whose TIN or TIN/NPIs are identified as

eligible during the first segment and do not exist in the second segment, are no longer utilizing these same TIN or TIN/NPI combinations. Therefore, because those TIN or TIN/NPIs would not exceed the low-volume threshold in the second segment, they would no longer be eligible for MIPS. For example, in the 2019 performance period a clinician exceeded the low-volume threshold during the first segment of the determination period (data from the end of CY 2017 to early 2018) under one TIN; then in CY 2019 the clinician switches practices under a new TIN and during segment two of the determination period. Therefore, it is determined that the clinician is not eligible (based on CY 2019 data) under either TIN. This clinician would not be eligible to participate in MIPS based on either segment of the determination period because the TIN that was assessed for the first segment of the determination period no longer exists. So there are no charges or services that would be available to assess in the second segment for that TIN and the new TIN assessed during the second segment was not eligible. In this scenario, though the clinician exceeded the low-volume threshold criteria initially, the clinician is not required to submit any data based on TIN eligibility determinations. However, it is important to note that if a TIN or TIN/NPI did not exist in the first segment but does exist in the second segment, these eligible clinicians could be eligible for MIPS. For example, the eligible clinician may not find their TIN or TIN/NPI in the Quality Payment Program lookup tool but may still be eligible if they exceed the low-volume threshold in the second segment. We proposed to incorporate this policy into our proposed definition of MIPS determination period at § 414.1305. We also request comments on our proposals to define MIPS determination period at § 414.1305 and modify the definitions of low-volume threshold, non-patient facing, a small practice, hospital-based, and ASC-based at § 414.1305 to incorporate references to the MIPS determination period.

c. Low-Volume Threshold

(1) Overview

Section 1848(q)(1)(C)(iv) of the Act, as amended by section 51003(a)(1)(A)(ii) of the Bipartisan Budget Act of 2018, provides that, for performance periods beginning on or after January 1, 2018, the low-volume threshold selected by the Secretary may include one or more or a combination of the following (as determined by the Secretary): (1) The

minimum number of part B-enrolled individuals who are furnished covered professional services (as defined in section 1848(k)(3)(A) of the Act) by the eligible clinician for the performance period involved; (2) the minimum number of covered professional services furnished to part B-enrolled individuals by such clinician for such performance period; and (3) the minimum amount of allowed charges for covered professional services billed by such clinician for such performance period.

Under § 414.1310(b)(1)(iii), for a year, eligible clinicians who do not exceed the low-volume threshold for the performance period with respect to a year are excluded from MIPS. Under § 414.1305, the low-volume threshold is defined as, for the 2019 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician or group that, during the low-volume threshold determination period, has Medicare Part B allowed charges less than or equal to \$30,000 or provides care for 100 or fewer Part B-enrolled Medicare beneficiaries. In addition, for the 2020 MIPS payment year and future years, the low-volume threshold is defined as the low-volume threshold that applies to an individual eligible clinician or group that, during the low-volume threshold determination period, has Medicare Part B allowed charges less than or equal to \$90,000 or provides care for 200 or fewer Part B-enrolled Medicare beneficiaries. The low-volume threshold determination period is a 24-month assessment period consisting of: (1) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period; and (2) a second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the low-volume threshold determination period includes a 60-day claims run out. For the 2020 MIPS payment year, each segment of the low-volume threshold determination period includes a 30-day claims run out.

(2) Proposed Amendments To Comply With the Bipartisan Budget Act of 2018

In this proposed rule, we are proposing to amend § 414.1305 to modify the definition of low-volume threshold in accordance with section 1848(q)(1)(C)(iv) of the Act, as amended by section 51003(a)(1)(A)(ii) of the Bipartisan Budget Act of 2018. Specifically, we request comments on our proposals that for the 2020 MIPS payment year, we will utilize the minimum number (200 patients) of Part B-enrolled individuals who are furnished covered professional services by the eligible clinician or group during the low-volume threshold determination period or the minimum amount (\$90,000) of allowed charges for covered professional services to Part B-enrolled individuals by the eligible clinician or group during the low-volume threshold determination period.

(3) MIPS Program Details

We request comments on our proposal to modify § 414.1310 to specify in paragraph (a), Program Implementation, that except as specified in paragraph (b), MIPS applies to payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019. We also request comments on our proposal to revise § 414.1310(b)(1)(ii) to specify that for a year, a MIPS eligible clinician does not include an eligible clinician that is a Partial Qualifying APM Participant (as defined in § 414.1305) and does not elect, as discussed in section III.H.4.e. of this proposed rule, to report on applicable measures and activities under MIPS. Finally, we request comments on our proposal to revise § 414.1310(d) to specify that, in no case will a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) apply to payments for covered professional services furnished during a year by eligible clinicians (including those described in paragraphs (b) and (c) of this section) who are not MIPS eligible clinicians, including those who voluntarily report on applicable measures and activities under MIPS.

(4) Proposed Addition of Low-Volume Threshold Criterion Based on Number of Covered Professional Services

In the CY 2018 Quality Payment Program final rule (82 FR 53591), we received several comments in response to the proposed rule regarding adding a third criterion of “items and services” for defining the low-volume threshold. We refer readers to that rule for further details.

For the 2021 MIPS payment year and future years, we are proposing to add one additional criterion to the low-volume threshold determination—the minimum number of covered professional services furnished to Part B-enrolled individuals by the clinician. Specifically, we request comments on our proposal, for the 2021 MIPS payment year and future years, that eligible clinicians or groups who meet at least one of the following three criteria during the MIPS determination period would not exceed the low-volume threshold: (1) Those who have allowed charges for covered professional services less than or equal to \$90,000; (2) those who provide covered professional services to 200 or fewer Part B-enrolled individuals; or (3) those who provide 200 or fewer covered professional services to Part B-enrolled individuals.

For the third criterion, we are proposing to set the threshold at 200 or fewer covered professional services furnished to Part B-enrolled individuals for several reasons. First, in the CY 2018 Quality Payment Program final rule (82 FR 53589 through 53590), while we received positive feedback from stakeholders on the increased low-volume threshold, we also heard from some stakeholders that they would like to participate in the program. Second, setting the third criterion at 200 or fewer covered professional services allows us to ensure that a significant number of eligible clinicians have the ability to opt-in if they wish to participate in MIPS. Finally, when we were considering where to set the low-volume threshold for covered professional services, we examined two options: 100 or 200 covered professional services. For 100 covered professional services, there is some historical precedent. In the CY 2017 Quality Payment Program final rule (81 FR 77062), we finalized a low-volume threshold that excluded individual eligible clinicians or groups that have Medicare Part B allowed charges less than \$30,000 or that provide care for 100 or fewer Part B-enrolled Medicare beneficiaries; we believe the latter criterion is comparable to 100 covered professional services. Conversely for 200 covered professional services, in the CY 2018 Quality Payment Program final rule comment period (82 FR 53588), we discussed that based on our data analysis, excluding individual eligible clinicians or groups that have Medicare Part B allowed charges less than or equal to \$90,000 or that provide care for 200 or fewer Part B-enrolled Medicare beneficiaries decreased the percentage

of MIPS eligible clinicians that come from small practices. In addition, in the CY 2018 Quality Payment final rule (82 FR 53955), we codified at § 414.1380(b)(1)(iv) a minimum case requirements for quality measures are 20 cases which both services threshold considerations (100 or 200) exceed and at § 414.1380(b)(1)(v) a minimum case requirements for the all-cause hospital readmission measure is 200 cases, which only the 200 services threshold consideration exceeds. We believe that setting a threshold of 200 services for the third criterion strikes the appropriate balance between allowing a significant number of eligible clinicians the ability to opt-in (as described below) to MIPS and consistency with the previously established low-volume threshold criteria. In section VII.F.8.b. of this proposed rule, we estimate no additional clinicians would be excluded if we add the third criterion because a clinician that cares for at least 200 beneficiaries would have at least 100 or 200 services; however, we estimate 42,025 clinicians would opt-in with the low-volume threshold at 200 services, as compared to 19,621 clinicians if we did not add the third criterion. If we set the third criterion at 100 services, then we estimate 50,260 clinicians would opt-in.

(5) Low-Volume Threshold Opt-In

In the CY 2018 Quality Payment Program final rule (82 FR 53589), we proposed the option to opt-in to MIPS participation if clinicians might otherwise be excluded under the low-volume threshold. We received general support from comments received in the CY 2018 Quality Payment Program final rule (82 FR 53589). However, we did not finalize the proposal for the 2019 MIPS performance period. We were concerned that we would not be able to operationalize this policy in a low-burden manner to MIPS eligible clinicians as it was proposed.

After consideration of operational and user experience implications of an opt-in policy, we are proposing an approach we believe can be implemented in a way that provides the least burden to clinicians. We are proposing to modify § 414.1310(b)(1)(iii) to provide that beginning with the 2021 MIPS payment year, if an eligible clinician or group meets or exceeds at least one, but not all, of the low-volume threshold determinations, including as defined by dollar amount (less than or equal to \$90,000) or number of beneficiaries (200 or fewer), or number of covered professional services (200 or fewer), then such eligible individual or group may choose to opt-in to MIPS.

This policy would apply to individual eligible clinicians and groups who exceed at least one, but not all, of the low-volume threshold criteria and would otherwise be excluded from MIPS participation as a result of the low-volume threshold. We believe that it would be beneficial to provide, to the extent feasible, such individual eligible clinicians and groups with the ability to opt-in to MIPS. Conversely, this policy would not apply to individual eligible clinicians and groups who exceed all of the low-volume threshold criteria, who unless otherwise excluded, are required to participate in MIPS. In addition, this policy would not apply to individual eligible clinicians and groups who do not exceed any of the low-volume threshold criteria, who would be excluded from MIPS participation without the ability to opt-in to MIPS. While we believe we are proposing the appropriate balance for the low-volume threshold elements, we request comments on other low-volume threshold criteria and supporting justification for the recommended criteria.

Under the proposed policies, we estimate clinician eligibility based on the following (we refer readers to the regulatory impact analysis in section VII.F.8.b. of this proposed rule for further details on our assumptions): (1) Eligible because they exceed all three criteria of the low-volume threshold and are not otherwise excluded (estimated 608,000 based on our assumptions of who did individual and group reporting); (2) eligible because they exceed at least one, but not all, of the low-volume threshold criteria and elect to opt-in (estimated 42,000 for a total MIPS eligible clinician population of approximately 650,000); (3) potentially eligible if they either did group reporting or elected to opt-in ¹⁵ (estimated 483,000); (4) excluded because they do not exceed any of the low-volume threshold criteria (estimated 88,000); and (5) excluded due to non-eligible specialty, newly

enrolled, or QP status (estimated 302,000).

We are proposing that applicable eligible clinicians who meet one or two, but not all, of the criteria to opt-in and are interested in participating in MIPS would be required to make a definitive choice to either opt-in to participate in MIPS or choose to voluntarily report before data submission. If they did not want to participate in MIPS, they would not be required to do anything and would be excluded from MIPS under the low-volume threshold. For those who did want to participate in MIPS, we considered the option of allowing the submission of data to signal that the clinician is choosing to participate in MIPS. However, we anticipated that some clinicians who utilize the quality data code (QDC) claims submission type may have their systems coded to automatically append QDCs on claims for eligible patients. We were concerned that they could submit a QDC code and inadvertently opt-in when that was not their intention.

For individual eligible clinicians and groups to make an election to opt-in or voluntarily report to MIPS, they would make an election via the Quality Payment Program portal by logging into their account and simply selecting either the option to opt-in (positive, neutral, or negative MIPS adjustment) or to remain excluded and voluntarily report (no MIPS adjustment). Once the eligible clinician has elected to participate in MIPS, the decision to opt-in to MIPS would be irrevocable and could not be changed for the applicable performance period. Clinicians who opt-in would be subject to the MIPS payment adjustment during the applicable MIPS payment year. Clinicians who do not decide to opt-in to MIPS would remain excluded and may choose to voluntarily report. Such clinicians would not receive a MIPS payment adjustment factor. To assist commenters in providing pertinent comments, we have developed a website that provides design examples of the

different approaches to MIPS participation in CY 2019. The website uses wireframe (schematic) drawings to illustrate the three different approaches to MIPS participation: Voluntary reporting to MIPS, opt-in reporting to MIPS, and required to participate in MIPS. We refer readers to the Quality Payment Program at qpp.cms.gov/design-examples to review these wireframe drawings. The website will provide specific matrices illustrating potential stakeholder experiences when opting-in or voluntarily reporting.

It should be noted that the option to opt-in to participate in the MIPS as a result of an individual eligible clinician or group exceeding at least one, but not all, of the low-volume threshold elements differs from the option to voluntarily report to the MIPS as established at § 414.1310(b)(2) and (d). Individual eligible clinicians and groups opting-in to participate in MIPS would be considered MIPS eligible clinicians, and therefore subject to the MIPS payment adjustment factor; whereas, individual eligible clinicians and groups voluntarily reporting measures and activities for the MIPS are not considered MIPS eligible clinicians, and therefore not subject to the MIPS payment adjustment factor. MIPS eligible clinicians and groups that made an election to opt-in would be able to participate in MIPS at the individual, group, or virtual group level for that performance period. Eligible clinicians and groups that are excluded from MIPS, but voluntarily report, are able to report measures and activities at the individual or group level; however, such eligible clinicians and groups are not able to voluntarily report for MIPS at the virtual group level.

In Table 28, we are providing possible scenarios regarding which eligible clinicians may be able to opt-in to MIPS depending upon their beneficiary count, dollars, and covered professional services if the proposed opt-in policy was finalized.

TABLE 28—LOW-VOLUME THRESHOLD DETERMINATION OPT-IN SCENARIOS

Beneficiaries	Dollars	Covered professional services	Eligible for opt-in
≤200	≤90K	≤200	Excluded not eligible to Opt-in.
≤200	≤90K	>200	Eligible to Opt-in, Voluntarily Report, or Not Participate.
≤200	>90K	≤200	Eligible to Opt-in, Voluntarily Report, or Not Participate.
>200	≤90K	>200	Eligible to Opt-in, Voluntarily Report, or Not Participate.
>200	>90K	>200	Not eligible to Opt-in, Required to Participate.

¹⁵ A clinician may be in a group that we estimated would not elect group reporting, however, the group would exceed the low-volume threshold on all three criteria if the group elected group

reporting. Similarly, an individual or group may exceed at least one but not all of the low-volume threshold criteria, but we estimated the clinician or group would not elect to opt-in to MIPS. In both

cases, these clinicians could be eligible for MIPS if the group or individual makes choices that differ from our assumptions.

We recognize that the low-volume threshold opt-in option may expand MIPS participation at the individual, group, and virtual group levels. For solo practitioners and groups with 10 or fewer eligible clinicians (including at least one MIPS eligible clinician) that exceed at least one, but not all, of the elements of the low-volume threshold and are interested in participating in MIPS via the opt-in and doing so as part of a virtual group, such solo practitioners and groups would need to make an election to opt-in to participate in the MIPS. Therefore, beginning with the 2021 MIPS payment year, we are proposing that a virtual group election would constitute a low-volume threshold opt-in for any prospective member of the virtual group (solo practitioner or group) that exceeds at least one, but not all, of the low-volume threshold criteria. As a result of the virtual group election, any such solo practitioner or group would be treated as a MIPS eligible clinician for the applicable MIPS payment year.

During the virtual group election process, the official virtual group representative of a virtual group submits an election to participate in the MIPS as a virtual group to CMS prior to the start of a performance period (82 FR 53601 through 53604). The submission of a virtual group election includes TIN and NPI information, which is the identification of TINs composing the virtual group and each member of the virtual group. As part of a virtual group election, the virtual group representative is required to confirm through acknowledgement that a formal written agreement is in place between each member of the virtual group (82 FR 53604). A virtual group may not include a solo practitioner or group as part of a virtual group unless an authorized person of the TIN has executed a formal written agreement.

For a solo practitioner or group that exceeds only one or two elements of the low-volume threshold, an election to opt-in to participate in the MIPS as part of a virtual group would be represented by being identified as a TIN that is included in the submission of a virtual group election. Such solo practitioners and groups opting-in to participate in the MIPS as part of a virtual group would not need to independently make a separate election to opt-in to participate in the MIPS. It should be noted that being identified as a TIN in a submitted virtual group election, any such TIN (represented as a solo practitioner or group) that exceeds at least one, but not all, of the low-volume threshold elements during the MIPS determination period is signifying an

election to opt-in to participate in MIPS as part of a virtual group and recognizing that a MIPS payment adjustment factor would be applied to any such TIN based on the final score of the virtual group. For a virtual group election that includes a TIN determined to exceed at least one, but not all, of the low-volume threshold elements during the MIPS determination period, such election would have a precedence over the eligibility determination made during the MIPS determination period pertaining to the low-volume threshold and as a result, any such TIN would be considered MIPS eligible and subject to a MIPS payment adjustment factor due the virtual group election. Furthermore, we note that a virtual group election would constitute an election to opt-in to participate in MIPS and any low-volume threshold determinations that result from segment 2 data analysis of the MIPS determination period would not have any bearing on the virtual group election. Thus, a TIN included as part of a virtual group election that submitted prior to the start of the applicable performance period and does not exceed at least one element of the low-volume threshold during segment 2 of the MIPS determination period, such TIN would be considered MIPS eligible and a virtual group participant by virtue of the virtual group's election to participate in MIPS as a virtual group that was made prior to the applicable performance period. For virtual groups with a composition that may only consist of solo practitioners and groups that exceed at least one, but not all of the low-volume threshold elements, such virtual groups are encouraged to form a virtual group that would include a sufficient number of TINs to ensure that such virtual groups are able to meet program requirements such as case minimum criteria that would allow measures to be scored. For example, if a virtual group does not have a sufficient number of cases to report for quality measures (minimum of 20 cases per episode-based measures), a virtual group would not be scored on such measures (81 FR 77175).

We further note that for APM Entities in MIPS APMs, which meet one or two, but not all, of the low-volume threshold elements to opt-in and are interested in participating in MIPS under the APM scoring standard, would be required to make a definitive choice at the APM Entity level to opt-in to participate in MIPS. For such APM Entities to make an election to opt-in to MIPS, they would make an election via a similar process that individual eligible clinicians and groups will use to make

an election to opt-in. Once the APM Entity has elected to participate in MIPS, the decision to opt-in to MIPS is irrevocable and cannot be changed for the performance period in which the data was submitted. Eligible clinicians in APM Entities in MIPS APMs that opt-in would be subject to the MIPS payment adjustment factor. APM Entities in MIPS APMs that do not decide to opt-in to MIPS cannot voluntarily report.

Additionally, we are proposing for applicable eligible clinicians participating in a MIPS APM, whose APM Entity meets one or two, but not all, of the low-volume threshold elements rendering the option to opt-in and does not decide to opt-in to MIPS, that if their TIN or virtual group does elect to opt-in, it does not mean that the eligible clinician is opting-in on his/her own behalf, or on behalf of the APM Entity, but that the eligible clinician is still excluded from MIPS participation as part of the APM Entity even though such eligible clinician is part of a TIN or virtual group. This is necessary because low-volume threshold determinations are currently conducted at the APM Entity level for all applicable eligible clinicians in MIPS APMs, and therefore, the low-volume threshold opt-in option should similarly be executed at the APM Entity level rather than at the individual eligible clinician, TIN, or virtual group level. Thus, in order for an APM Entity to opt-in to participate in MIPS at the APM Entity level and for eligible clinicians within such APM Entity to be subject to the MIPS payment adjustment factor, an election would need to be made at the APM Entity level in a similar process that individual eligible clinicians and groups would use to make an election to opt-in to participate in MIPS.

We request comments on our proposals: (1) To modify § 414.1305 for the low-volume threshold definition at (3) to specify that, beginning with the 2021 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician or group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to \$90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals; (2) that a clinician who is eligible to opt-in would be required to make an affirmative election to opt-in to participate in MIPS, elect to be a voluntary reporter, or by not submitting any data the clinician is choosing to not report; and (3) to modify

§ 414.1310(b)(1)(iii) under Applicability to specify exclusions as follows: Beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to report on applicable measures and activities under MIPS, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated as MIPS eligible clinicians for the applicable payment year.

(6) Part B Services Subject to MIPS Payment Adjustment

Section 1848(q)(6)(E) of the Act, as amended by section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018, provides that the MIPS adjustment factor and, as applicable, the additional MIPS adjustment factor, apply to the amount otherwise paid under Part B with respect to covered professional services (as defined in subsection (k)(3)(A) of the Act) furnished by a MIPS eligible clinician during a year (beginning with 2019) and with respect to the MIPS eligible clinician for such year.

In this proposed rule, we are requesting comments on our proposal to amend § 414.1405(e) to modify the application of both the MIPS adjustment factor and, if applicable, the additional MIPS adjustment factor so that beginning with the 2019 MIPS payment year, these adjustment factors will apply to Part B payments for covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by the MIPS eligible clinician during the year. We are making this change beginning with the first MIPS payment year and note that these adjustment factors will not apply to Part B drugs and other items furnished by a MIPS eligible clinician, but will apply to covered professional services furnished by a MIPS eligible clinician. We refer readers to section III.H.3.j. of this proposed rule for further details on this modification.

d. Partial QPs

(1) Partial QP Elections Within Virtual Groups

In the CY 2017 Quality Payment Program final rule, we finalized that following a determination that eligible clinicians in an APM Entity group in an Advanced APM are Partial QPs for a year, the APM Entity will make an

election whether to report on applicable measures and activities as required under MIPS. If the APM Entity elects to report to MIPS, all eligible clinicians in the APM Entity would be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the APM Entity elects not to report, all eligible clinicians in the APM Entity group will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year (81 FR 77449).

We also finalized that in cases where the Partial QP determination is made at the individual eligible clinician level, if the individual eligible clinician is determined to be a Partial QP, the eligible clinician will make the election whether to report on applicable measures and activities as required under MIPS and, as a result, be subject to the MIPS reporting requirements and payment adjustments (81 FR 77449). If the individual eligible clinician elects to report to MIPS, he or she would be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the individual eligible elects not to report to MIPS, he or she will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year. We also clarified how we consider the absence of an explicit election to report to MIPS or to be excluded from MIPS. We finalized that for situations in which the APM Entity is responsible for making the decision on behalf of all eligible clinicians in the APM Entity group, the group of Partial QPs will not be considered MIPS eligible clinicians unless the APM Entity opts the group into MIPS participation, so that no actions other than the APM Entity's election for the group to participate in MIPS would result in MIPS participation (81 FR 77449). For eligible clinicians who are determined to be Partial QPs individually, we finalized that we will use the eligible clinician's actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election. Therefore, if an eligible clinician who is individually determined to be a Partial QP submits information to MIPS (not including information automatically populated or calculated by CMS on the Partial QP's behalf), we will consider the Partial QP to have reported, and thus to be participating in MIPS. Likewise, if such an individual does not take any action to submit information to MIPS, we will consider the Partial QP to have elected to be excluded from MIPS (81 FR 77449).

In the CY 2018 Quality Payment Program final rule, we clarified that in the case of an eligible clinician participating in both a virtual group and an Advanced APM who has achieved Partial QP status, that the eligible clinician would be excluded from the MIPS payment adjustment unless the eligible clinician elects to report under MIPS (82 FR 53615). However, we incorrectly stated that affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period would constitute an explicit election to report under MIPS for all Partial QPs. As such, we also incorrectly stated that all eligible clinicians who participate in a virtual group and achieve Partial QP status would remain subject to the MIPS payment adjustment due to their virtual group election to report under MIPS, regardless of their Partial QP election. We note that an election made prior to the start of an applicable performance period to participate in MIPS as part of a virtual group is separate from an election made during the performance period that is warranted as a result of an individual eligible clinician or APM Entity achieving Partial QP status during the applicable performance period. A virtual group election does not equate to an individual eligible clinician or APM Entity with a Partial QP status explicitly electing to participate in MIPS. In order for an individual eligible clinician or APM Entity with a Partial QP status to explicitly elect to participate in MIPS and be subject to the MIPS payment adjustment factor, such individual eligible clinician or APM Entity would make such election during the applicable performance period as a Partial QP status becomes applicable and such option for election is warranted. Thus, we are restating that affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period does not constitute an explicit election to report under MIPS as it pertains to making an explicit election to either report to MIPS or be excluded from MIPS for individual eligible clinicians or APM Entities that have Partial QP status.

Related to this clarification, we have proposed in section III.H.4.e.(3) of this proposed rule to clarify that beginning with the 2021 MIPS payment year, when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report

to MIPS, he or she will be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician elects to not report to MIPS, he or she will not be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician does not make any affirmative election to report to MIPS, he or she will not be subject to MIPS reporting requirements and payment adjustments. As a result, beginning with the 2021 MIPS payment year, for eligible clinicians who are determined to be Partial QPs individually, we will not use the eligible clinician's actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election.

Therefore, the proposed policy in section III.H.4.e.(3) of this proposed rule eliminates the scenario in which affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period would constitute an explicit election to report under MIPS for eligible clinicians who are determined to be Partial QPs individually and make no explicit election to either report to MIPS or be excluded from MIPS. We believe this change is necessary because QP status and Partial QP status, achieved at the APM Entity level or eligible clinician level, is applied to an individual and all of his or her TIN/NPI combinations, whereas virtual group participation is determined at the TIN level. Therefore, we do not believe that it is appropriate that the actions of the TIN in joining the virtual group should deprive the eligible clinician who is a Partial QP, whether that status was achieved at APM Entity level or eligible clinician level, of the opportunity to elect whether or not to opt-in to MIPS.

e. Group Reporting

We refer readers to § 414.1310(e) and the CY 2018 Quality Payment Program final rule (82 FR 53592 through 53593) for a description of our previously established policies regarding group reporting.

In the CY 2018 Quality Payment Program final rule (82 FR 53593), we clarified that we consider a group to be either an entire single TIN or portion of a TIN that: (1) Is participating in MIPS according to the generally applicable scoring criteria while the remaining portion of the TIN is participating in a MIPS APM or an Advanced APM according to the MIPS APM scoring standard; and (2) chooses to participate in MIPS at the group level. We would like to further clarify that we consider a group to be an entire single TIN that chooses to participate in MIPS at the

group level. However, individual eligible clinicians (TIN/NPIs) within that group may receive a MIPS payment adjustment based on the APM scoring standard if they are on the participant list of a MIPS APM. We are proposing to amend §§ 414.1310(e) and 414.1370(f)(2) to codify this policy and more fully reflect the scoring hierarchy as discussed in section III.H.3.h.(6) of this proposed rule.

As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53593), one of the overarching themes we have heard from stakeholders is that we make an option available to groups that would allow a portion of a group to report as a separate sub-group on measures and activities that are more applicable to the sub-group and be assessed and scored accordingly based on the performance of the sub-group. We stated that in future rulemaking, we intend to explore the feasibility of establishing group-related policies that would permit participation in MIPS at a sub-group level and create such functionality through a new identifier. In the CY 2018 Quality Payment Program proposed rule (82 FR 30027), we solicited public comments on the ways in which participation in MIPS at the sub-group level could be established. In addition, in the CY 2018 Quality Payment Program final rule (82 FR 53593), we sought comment on additional ways to define a group, not solely based on a TIN. Because there are several operational challenges with implementing a sub-group option, we are not proposing any such changes to our established reporting policies in this proposed rule. Rather, we are considering facilitating the use of a sub-group identifier in the Quality Payment Program Year 4 through future rulemaking, as necessary. In addition, it has come to our attention that providing a sub-group option may provide potential gaming opportunities. For example, a group could manipulate scoring by creating sub-groups that are comprised of only the high performing clinicians in the group. Therefore, we are requesting comment on implementing sub-group level reporting through a separate sub-group sub-identifier in the Quality Payment Program Year 4 and possibly future years of the program. We are specifically requesting comments on the following: (1) Whether and how a sub-group should be treated as a separate group from the primary group: For example, if there is 1 sub-group within a group, how would we assess eligibility, performance, scoring, and application of the MIPS payment adjustment at the

sub-group level; (2) whether all of the sub-group's MIPS performance data should be aggregated with that of the primary group or should be treated as a distinct entity for determining the sub-group's final score, MIPS payment adjustments, and public reporting, and eligibility be determined at the whole group level; (3) possible low burden solutions for identification of sub-groups: For example, whether we should require registration similar to the CMS Web Interface or a similar mechanism to the low-volume threshold opt-in that we are proposing in section III.H.3.c.(5) of this proposed rule; and (4) and potential issues or solutions needed for sub-groups utilizing submission mechanisms, measures, or activities, such as APM participation, that are different than the primary group. We also welcome comments on other approaches for sub-group reporting that we should consider.

f. Virtual Groups

(1) Background

We refer readers to § 414.1315 and the CY 2018 Quality Payment Program final rule (82 FR 53593 through 53617) for our previously established policies regarding virtual groups.

(2) Virtual Group Election Process

We refer readers to § 414.1315(c) and the CY 2018 Quality Payment Program final rule (82 FR 53601 through 53604) for our previously established policies regarding the virtual group election process.

We are proposing to amend § 414.1315(c) to continue to apply the previously established policies regarding the virtual group election process for the 2022 MIPS payment year and future years, with the exception of the proposed policy modification discussed below.

Under § 414.1315(c)(2)(ii), an official designated virtual group representative must submit an election on behalf of the virtual group by December 31 of the calendar year prior to the start of the applicable performance period. In the CY 2018 Quality Payment Program final rule (82 FR 53603), we stated that such election will occur via email to the Quality Payment Program Service Center using the following email address for the 2018 and 2019 performance periods: *MIPS_VirtualGroups@cms.hhs.gov*. Beginning with the 2022 MIPS payment year, we propose to amend § 414.1315(c)(2)(ii) to provide that the election would occur in a manner specified by CMS. We anticipate that a virtual group representative would make an election

on behalf of a virtual group by registering to participate in MIPS as a virtual group via a web-based system developed by CMS. We believe that a web-based system would be less burdensome for virtual groups given that the interactions stakeholders would have with the Quality Payment Program are already conducted via the Quality Payment Program portal, and would provide stakeholders with a seamless user experience. Stakeholders would be able to make a virtual group election in a similar manner to all other interactions with the Quality Payment Program portal and would no longer need to separately identify the appropriate email address to submit such an election and email an election outside of the Quality Payment Program portal. The Quality Payment Program portal is the gateway and source for interaction with MIPS that contains a range of information on topics including eligibility, data submission, and performance reports. We believe that using the same web-based platform to make a virtual group election would enhance the one-stop MIPS interactive experience and eliminate the potential for stakeholders to be unable to identify or erroneously enter the email address.

We solicit public comment on this proposal, which would provide for an election to occur in a manner specified by CMS such as a web-based system developed by CMS.

(a) Virtual Group Eligibility Determinations

For purposes of determining TIN size for virtual group participation eligibility for the CY 2018 and 2019 performance periods, we coined the term “virtual group eligibility determination period” and defined it to mean an analysis of claims data during an assessment period of up to 5 months that would begin on July 1 and end as late as November 30 of the calendar year prior to the applicable performance period and includes a 30-day claims run out (82 FR 53602). We are proposing to modify the virtual group eligibility determination period beginning with the 2019 performance period. We propose to amend § 414.1315(c)(1) to establish a virtual group eligibility determination period to mean an analysis of claims data during a 12-month assessment period (fiscal year) that would begin on October 1 of the calendar year 2 years prior to the applicable performance period and end on September 30 of the calendar year preceding the applicable performance period and include a 30-day claims run out. The virtual group eligibility determination period aligns with the first segment of data analysis

under the MIPS eligibility determination period. As part of the virtual group eligibility determination period, TINs would be able to inquire about their TIN size prior to making an election during a 5-month timeframe, which would begin on August 1 and end on December 31 of a calendar year prior to the applicable performance period. TIN size inquiries would be made through the Quality Payment Program Service Center. For TINs that inquire about their TIN size during such 5-month timeframe, it should be noted that any TIN size information provided is only for informational purposes and may be subject to change; official eligibility regarding TIN size and all other eligibility pertaining to virtual groups would be determined in accordance with the MIPS determination period and other applicable special status eligibility determination periods. The proposed modification would provide stakeholders with real-time information regarding TIN size for informational purposes instead of TIN size eligibility determinations on an ongoing basis (between July 1 and November 30 of the calendar year prior to the applicable performance period) due to technical limitations.

For the 2018 and 2019 performance periods, TINs could determine their status by contacting their designated TA representative as provided at § 414.1315(c)(1); otherwise, the TIN's status would be determined at the time that the TIN's virtual group election is submitted. We propose to amend § 414.1315(c)(1) to remove this provision since the inquiry about TIN size would be for informational purposes only and may be subject to change.

We believe that the utilization of the Quality Payment Program Service Center, versus the utilization of designated TA representatives, as the means for stakeholders to obtain information regarding TIN size provides continuity and a seamless experience for stakeholders. We note that the TA resources already available to stakeholders would continue to be available. The following describes the experience a stakeholder would encounter when interacting with the Quality Payment Program Service Center to obtain information pertaining to TIN size. For example, the applicable performance period for the 2022 MIPS payment year would be CY 2020. If a group contacted the Quality Payment Program Service Center on September 20, 2019, the claims data analysis would include the months of October of 2018 through August of 2019. If another

group contacted the Quality Payment Program Service Center on November 20, 2019, the claims data analysis would include the months of October of 2018 through September of 2019 with a 30-day claims run out.

We believe this virtual group eligibility determination period provides a real-time representation of TIN size for purposes of determining virtual group eligibility and allows solo practitioners and groups to know their real-time virtual group eligibility status and plan accordingly for virtual group implementation. Beginning with the 2022 MIPS payment year, it is anticipated that starting in August of each calendar year prior to the applicable performance period, solo practitioners and groups would be able to contact the Quality Payment Program Service Center and inquire about their TIN size. TIN size determinations would be based on the number of NPIs associated with a TIN, which may include clinicians (NPIs) who do not meet the definition of a MIPS eligible clinician at § 414.1305 or who are excluded from MIPS under § 414.1310(b) or (c).

We are proposing to continue to apply the aforementioned previously established virtual group policies for the 2022 MIPS payment year and future years, with the exception of the following proposed policy modifications:

- The virtual group eligibility determination period would align with the first segment of the MIPS determination period, which includes an analysis of claims data during a 12-month assessment period (fiscal year) that would begin on October 1 of the calendar year 2 years prior to the applicable performance period and end on September 30 of the calendar year preceding the applicable performance period and include a 30-day claims run out. As part of the virtual group eligibility determination period, TINs would be able to inquire about their TIN size prior to making an election during a 5-month timeframe, which would begin on August 1 and end on December 31 of a calendar year prior to the applicable performance period.

- MIPS eligible clinicians would be able to contact their designated technical assistance representative or, beginning with the 2022 MIPS payment year, the Quality Payment Program Service Center, as applicable, to inquire about their TIN size for informational purposes in order to assist MIPS eligible clinicians in determining whether or not to participate in MIPS as part of a virtual group. We anticipate that starting in August of each calendar year prior to

the applicable performance period, solo practitioners and groups would be able to contact the Quality Payment Program Service Center and inquire about virtual group participation eligibility.

- A virtual group representative would make an election on behalf of a virtual group by registering to participate in MIPS as a virtual group in a form and manner specified by CMS. We anticipate that a virtual group representative would make the election via a web-based system developed by CMS.

We are also proposing updates to § 414.1315 in an effort to more clearly and concisely capture previously established policies. These proposed updates are not intended to be substantive in nature, but rather to bring more clarity to the regulatory text.

g. MIPS Performance Period

In the CY 2018 Quality Payment Program final rule (82 FR 53617 through 53619), we finalized at § 414.1320(c)(1) that for purposes of the 2021 MIPS payment year, the performance period for the quality and cost performance categories is CY 2019 (January 1, 2019 through December 31, 2019). We did not finalize the performance period for the quality and cost performance categories for purposes of the 2022 MIPS payment year or future years. We also redesignated § 414.1320(d)(1) and finalized at § 414.1320(c)(2) that for purposes of the 2021 MIPS payment year, the performance period for the Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2019, up to and including the full CY 2019 (January 1, 2019 through December 31, 2019).

As noted in the CY 2018 Quality Payment Program final rule, we received comments that were not supportive of a full calendar year performance period for the quality and cost performance categories. However, we continue to believe that a full calendar year performance period for the quality and cost performance categories will be less confusing for MIPS eligible clinicians. Further, a longer performance period for the quality and cost performance categories will likely include more patient encounters, which will increase the denominator of the quality and cost measures. Statistically, larger sample sizes provide more accurate and actionable information. Additionally, a full calendar year performance period is consistent with how many of the measures used in our program were designed to be performed and reported. We also note that the Bipartisan Budget Act of 2018 (Pub. L. 115–119, enacted

on February 9, 2018) has provided further flexibility to the third, fourth, and fifth years to which MIPS applies to help continue the gradual transition to MIPS.

Regarding the Promoting Interoperability performance category, we have heard from stakeholders through public comments, letters, and listening sessions that they oppose a full year performance period, indicating that it is very challenging and may add administrative burdens. Some stated that a 90-day performance period is necessary in order to enable clinicians to have a greater focus on the objectives and measures that promote patient safety, support clinical effectiveness, and drive toward advanced use of health IT. They also noted that as this category requires the use of CEHRT, a 90-day performance period will help relieve pressure on clinicians to quickly implement changes and updates from their CEHRT vendors and developers so that patient care is not compromised. Others cited the challenges associated with reporting on a full calendar year for clinicians newly employed by a health system or practice during the course of a program year, switching CEHRT, vendor issues, system downtime, cyber-attacks, difficulty getting data from old places of employment, and office relocation. Most stakeholders stated that the performance period should be 90 days in perpetuity, as this would greatly reduce the reporting burden.

In an effort to provide as much transparency as possible so that MIPS eligible clinicians and groups can plan for participation in the program, we request comments on our proposals at § 414.1320(d)(1) that for purposes of the 2022 MIPS payment year and future years, the performance period for the quality and cost performance categories would be the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year. For example, for the 2022 MIPS payment year, the performance period would be 2020 (January 1, 2020 through December 31, 2020), and for the 2023 MIPS payment year, the performance period would be CY 2021 (January 1, 2021 through December 31, 2021).

We request comments on our proposal at § 414.1320(d)(2) that for purposes of the 2022 MIPS payment year and future years, the performance period for the improvement activities performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar

year. For example, for the 2022 MIPS payment year, the performance period for the improvement activities performance category would be a minimum of a continuous 90-day period within CY 2020, up to and including the full CY 2020 (January 1, 2020 through December 31, 2020). For the 2023 MIPS payment year, the performance period for the improvement activities performance category would be a minimum of a continuous 90-day period within CY 2021, up to and including the full CY 2021 (January 1, 2021 through December 31, 2021) that occurs 2 years before the MIPS payment year.

In addition, we request comments on our proposal to add § 414.1320(e)(1) that for purposes of the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of a continuous 90-day period within CY 2020, up to and including the full CY 2020 (January 1, 2020 through December 31, 2020).

h. MIPS Performance Category Measures and Activities

(1) Performance Category Measures and Reporting

(a) Background

We refer readers to § 414.1325 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77087 through 77095, and 82 FR 53619 through 53626, respectively) for our previously established policies regarding data submission requirements.

(b) Collection Types, Submission Types and Submitter Types

It has come to our attention that the way we have previously described data submission by MIPS eligible clinicians, groups and third party intermediaries does not precisely reflect the experience users have when submitting data to us. To clarify, we have previously used the term “submission mechanisms” to refer not only to the mechanism by which data is submitted, but also to certain types of measures and activities on which data are submitted (for example, electronic clinical quality measures (eCQMs) reported via EHR) and to the entities submitting such data (for example, third party intermediaries on behalf of MIPS eligible clinicians and groups). To ensure clarity and precision

for all users, we are proposing to revise existing and define additional terminology to more precisely reflect the experience users have when submitting data to the Quality Payment Program.

At § 414.1305, we propose to define the following terms:

- Collection type as a set of quality measures with comparable specifications and data completeness criteria, including, as applicable: eCQMs; MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. The term MIPS CQMs would replace what was formerly referred to as registry measures since entities other than registries may submit data on these measures. These new terms are referenced in the collection type field for the following measure tables of the appendices in this proposed rule: Table Group A: Proposed New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years; Table Group B: Proposed New and Modified MIPS Specialty Measure Sets for the 2021 MIPS Payment Year and Future Years; Table C: Quality Measures Proposed for Removal from the Merit-Based Incentive Payment System Program for the 2019 Performance Period and Future Years; and Table Group D: Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years.

- Submitter type as the MIPS eligible clinician, group, or third party intermediary acting on behalf of a MIPS eligible clinician or group, as applicable, that submits data on measures and activities under MIPS.

- Submission type as the mechanism by which a submitter type submits data to CMS, including, as applicable: Direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface. The direct submission type allows users to transmit data through a computer-to-computer interaction, such as an API. The log in and upload submission type allows users to upload and submit data in the form and manner specified by CMS with a set of authenticated credentials. The log in and attest submission type allows users to manually attest that certain measures and activities were performed in the form and manner specified by CMS with a set of authenticated credentials. We note that there is no submission type for the administrative claims collection type because we calculate measures for this collection type based on administrative claims data available to us.

We solicit additional feedback and alternative suggestions on terminology that appropriately reflects the concepts described in the proposed definitions of collection type, submitter type and submission type, as well as the term MIPS CQMs to replace the formerly used term of registry measures.

We previously finalized at § 414.1325(a) and (e), respectively, that MIPS eligible clinicians and groups must submit measures, objectives, and activities for the quality, improvement activities, and advancing care information performance categories and that there are no data submission requirements for the cost performance category and for certain quality measures used to assess performance in the quality performance category; CMS will calculate performance on these measures using administrative claims data. We propose to amend § 414.1325(a) to incorporate § 414.1325(e), as they both address which performance categories require data submission; § 414.1325(f) would be redesignated as § 414.1325(e). We also propose at § 414.1325(a)(2)(ii) that there is no data submission requirement for the quality or cost performance category, as applicable, for MIPS eligible clinicians and groups that are scored under the facility-based measurement scoring methodology described in § 414.1380(e). We also recognize the need to clarify to users how they submit data to us. There are five basic submission types that we are proposing to define in MIPS: Direct; log in and upload; log in and attest; Medicare Part B claims; and the CMS Web Interface. We are proposing to reorganize § 414.1325(b) and (c) by performance category. We are proposing to clarify at § 414.1325(b)(1) that an individual MIPS eligible clinician may submit their MIPS data for the quality performance category using the direct, login and upload, and Medicare Part B claims submission types. Similarly, we are proposing to clarify at § 414.1325(b)(2) that an individual MIPS eligible clinician may submit their MIPS data for the improvement activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types. As for groups, we propose to clarify at § 414.1325(c)(1) that groups may submit their MIPS data for the quality performance category using the direct, login and upload, and CMS Web Interface (for groups consisting of 25 or more eligible clinicians) submission types. Lastly, we propose to clarify at § 414.1325(c)(2) that groups may submit their MIPS data for the improvement

activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types. We believe that these clarifications will enhance the submission experience for clinicians and other stakeholders. As technology continues to evolve, we will continue to look for new ways that we can offer further technical flexibilities on submitting data to the Quality Payment Program. We request comment on these proposals. To assist commenters in providing pertinent comments, we have developed a website that uses wireframe (schematic) drawings to illustrate a subset of the different submission types available for MIPS participation. Specifically, the wireframe drawings describe the direct, login and attest, and login and upload submission types. We refer readers to the Quality Payment Program at qpp.cms.gov/design-examples to review these wireframe drawings. The website will provide specific matrices illustrating potential stakeholder experiences when choosing to submit data under MIPS.

As previously expressed in the 2017 Quality Payment Program final rule (81 FR 77090), we want to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. While we would like to move towards the utilization of electronic reporting by all clinicians and groups, we realize that small practices face additional challenges, and this requirement may limit their ability to participate. For this reason, we believe that Medicare Part B claims measures should be available to small practices, regardless of whether they are reporting an individual MIPS eligible clinician or as groups. Therefore, we propose amending § 414.1325(c)(1) to make the Medicare Part B claims collection type available to MIPS eligible clinicians in small practices beginning with the 2021 MIPS payment year. While this would limit the current availability of Medicare Part B claims measures for individual MIPS eligible clinicians, it would expand the availability of such measures for groups, which currently do not have any claims-based reporting option.

Under § 414.1325(c)(4), we previously finalized that groups may submit their MIPS data using the CMS Web Interface (for groups consisting of 25 or more eligible clinicians) for the quality, improvement activities, and promoting interoperability performance categories. We are proposing that the CMS Web Interface submission type would no longer be available for groups to use to submit data for the improvement activities and Promoting Interoperability

performance categories at § 414.1325(c)(2). The CMS Web Interface has been designed based on user feedback as a method for quality submissions only; however, groups that elect to utilize the CMS Web Interface can still submit improvement activities or promoting interoperability data via direct, log in and attest or log in and upload submission types. We also recognize that certain groups that have elected to use the CMS Web Interface may prefer to have their data submitted on their behalf by a third party intermediary described at § 414.1400(a). We recognize the benefit and burden reduction in such a flexibility and therefore propose to allow third party intermediaries to submit data to the CMS Web Interface in addition to groups. Specifically, we propose to redesignate § 414.1325(c)(4) as § 414.1325(c)(1) and amend § 414.1325(c)(1) to allow third party intermediaries to submit data using the CMS Web Interface on behalf of groups.

To further our efforts to provide flexibility in reporting to the Quality Payment Program, we are soliciting comment on expanding the CMS Web Interface submission type to groups consisting of 16 or more eligible clinicians to inform our future rulemaking.

We previously finalized at § 414.1325(e) that there are no data submission requirements for the cost performance category and for certain quality measures used to assess performance in the quality performance category and that CMS will calculate performance on these measures using administrative claims data. We also finalized at § 414.1325(f)(2), (which, as noted, we are proposing to redesignate as § 414.1325(e)(2)) that for Medicare Part B claims, data must be submitted on claims with dates of service during the performance period that must be processed no later than 60 days following the close of the performance period. We neglected to codify this

requirement at § 414.1325(e) (which, as noted, we are proposing to consolidate with § 414.1325(a)) for administrative claims data used to assess performance in the cost performance category and for administrative claims-based quality measures. Therefore, we propose to amend § 414.1325(a)(2)(i) to reflect that claims included in the measures are those submitted with dates of service during the performance period that are processed no later than 60 days following the close of the performance period.

A summary of these proposed changes is included in Tables 29 and 30. For reference, Table 29 summarizes the data submission types for individual MIPS eligible clinicians that we are proposing at § 414.1325(b) and (e). Table 30 summarizes the data submission types for groups that we are proposing at § 414.1325(c) and (e). We request comment on these proposals.

TABLE 29—DATA SUBMISSION TYPES FOR MIPS ELIGIBLE CLINICIANS REPORTING AS INDIVIDUALS

Performance category/submission combinations accepted	Submission type	Submitter type	Collection type
Quality	Direct Log in and upload	Individual or Third Party Intermediary ² .	eCQMs. MIPS CQMs. QCDR measures. Medicare Part B claims measures (small practices).
Cost	Medicare Part B claims (small practices) ¹ . No data submission required ²	Individual	
Promoting Interoperability	Direct Log in and upload. Log in and attest.	Individual or Third Party Intermediary.	
Improvement Activities	Direct Log in and upload. Log in and attest.	Individual or Third Party Intermediary.	

¹ Third party intermediary does not apply to Medicare Part B claims submission type.

² Requires no separate data submission to CMS: Measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare claims.

Note: As used in this proposed rule, the term "Medicare Part B claims" differs from "administrative claims" in that "Medicare Part B claims" require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.

TABLE 30—DATA SUBMISSION TYPES FOR MIPS ELIGIBLE CLINICIANS REPORTING AS GROUPS

Performance category/submission combinations accepted	Submission types	Submitter type	Collection type
Quality	Direct Log in and upload CMS Web Interface (groups of 25 or more eligible clinicians) Medicare Part B claims (small practices) ¹ .	Group or Third Party Intermediary	eCQMs. MIPS CQMs. QCDR measures. CMS Web Interface measures. Medicare Part B claims measures (small practices). CMS approved survey vendor measure. Administrative claims measures.
Cost	No data submission required ^{1 2} ...	Group.	
Promoting Interoperability	Direct Log in and upload. Log in and attest.	Group or Third Party Intermediary.	

TABLE 30—DATA SUBMISSION TYPES FOR MIPS ELIGIBLE CLINICIANS REPORTING AS GROUPS—Continued

Performance category/submission combinations accepted	Submission types	Submitter type	Collection type
Improvement Activities	Direct Log in and upload. Log in and attest.	Group or Third Party Intermediary.	

¹ Third party intermediary does not apply to Medicare Part B claims submission type.

² Requires no separate data submission to CMS: Measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare claims. **Note:** As used in this proposed rule, the term "Medicare Part B claims" differs from "administrative claims" in that "Medicare Part B claims" require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.

(c) Submission Deadlines

We previously finalized data submission deadlines in the CY 2017 Quality Payment Program final rule (81 FR 77095 through 77097) at § 414.1325(f), which outlined data submission deadlines for all submission mechanisms for individual eligible clinicians and groups for all performance categories. As discussed in section III.H.3.h.(1) of this proposed rule, the term submission mechanism, that includes submission via the qualified registry, QCDR, EHR, Medicare Part B claims, the CMS Web Interface and attestation, does not align with the existing process of data submission to the Quality Payment Program. We are proposing to revise regulatory text language at § 414.1325(f), which, as noted, we are proposing to redesignate as § 414.1325(e), to outline data submission deadlines for all submission types for individual eligible clinicians and groups for all performance categories. We also propose to revise § 414.1325(e)(1) to allow flexibility for CMS to alter submission deadlines for the direct, login and upload, the CMS Web Interface, and login and attest submission types. We anticipate that in scenarios where the March 31st deadline falls on a weekend or holiday, we would extend the submission period to the next business day (that is, Monday). There also may be instances where due to unforeseen technical issues, the submission system may be inaccessible for a period of time. If this scenario were to occur, we anticipate that we would extend the submission period to account for this lost time, to the extent feasible. We note that this revision would also revise the previously finalized policy at § 414.1325(e)(3) stating that data must be submitted during an 8-week period following the close of the performance period, and that the period must begin no earlier than January 2 and end no later than March 31 for the CMS Web Interface. We are proposing to align the deadline for the CMS Web Interface submission type with all other

submission type deadlines at § 414.1325(e)(1), while we are also proposing to remove the previously finalized policy at § 414.1325(e)(3) because it is no longer needed to mandate a different submission deadline for the CMS Web Interface submission type.

We are also proposing a number of other technical revisions to § 414.1325 to more clearly and concisely reflect previously established policies.

(2) Quality Performance Category

(a) Background

We refer readers to §§ 414.1330 through 414.1340 and the CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641) for our previously established policies regarding the quality performance category.

(i) Assessing Performance on the Quality Performance Category

Under § 414.1330(a), for purposes of assessing performance of MIPS eligible clinicians on the quality performance category, we will use: Quality measures included in the MIPS final list of quality measures and quality measures used by QCDRs. We are proposing to amend § 414.1330(a) to account for facility-based measurement and the APM scoring standard. For that reason, we are proposing § 414.1330(a) to specify, for a MIPS payment year, we use the following quality measures, as applicable, to assess performance in the quality performance category: Measures included in the MIPS final list of quality measures established by us through rulemaking; QCDR measures approved by us under § 414.1440; facility-based measures as described under § 414.1380; and MIPS APM measures as described at § 414.1370.

(ii) Contribution to Final Score

Under § 414.1330(b)(2) and (3), performance in the quality performance category will comprise 50 percent of a MIPS eligible clinician's final score for the 2020 MIPS payment year and 30 percent of a MIPS eligible clinician's

final score for each MIPS payment year thereafter. Section 1848(q)(5)(E)(i)(I) of the Act, as amended by section 51003(a)(1)(C)(i) of the Bipartisan Budget Act of 2018, provides that 30 percent of the final score shall be based on performance with respect to the quality performance category, but that for each of the first through fifth years for which MIPS applies to payments, the quality performance category performance percentage shall be increased so that the total percentage points of the increase equals the total number of percentage points by which the cost performance category performance percentage is less than 30 percent for the respective year. As discussed in section III.H.3.i.(c) of this proposed rule, we are proposing to weight the cost performance category at 15 percent for the 2021 MIPS payment year. Accordingly, we are proposing to amend § 414.1330(b)(2) to provide that performance in the quality performance category will comprise 50 percent of a MIPS eligible clinician's final score for the 2020 MIPS payment year, and propose at § 414.1330(b)(3) that the quality performance category comprises 45 percent of a MIPS eligible clinician's final score for the 2021 MIPS payment year.

(iii) Quality Data Submission Criteria

(A) Submission Criteria

(aa) Submission Criteria for Groups Reporting Quality Measures, Excluding CMS Web Interface Measures and the CAHPS for MIPS Survey Measure

We refer readers to § 414.1335(a)(1) for our previously established submission criteria for quality measures submitted via claims, registry, QCDR, or EHR. In section III.H.3.h. of this proposed rule, we propose revisions to existing and additional terminology to clarify the data submission processes available for MIPS eligible clinicians, groups and third party intermediaries, to align with the way users actually submit data to the Quality Payment Program. For that reason, we are proposing to revise § 414.1335(a)(1) to

state that data would be collected for the following collection types: Medicare Part B claims measures; MIPS CQMs; eCQMs, or QCDR measures. Codified at § 414.1335(a)(1)(i), MIPS eligible clinicians and groups must submit data on at least six measures including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician or group, report on each measure that is applicable. Furthermore, we are proposing beginning with the 2021 MIPS payment year to revise § 414.1335(a)(1)(ii) to indicate that MIPS eligible clinicians and groups that report on a specialty or subspecialty measure set, must submit data on at least six measures within that set, provided the set contain at least six measures. If the set contains fewer than six measures or if fewer than six measures apply to the MIPS eligible clinician or group, report on each measure that is applicable.

As previously expressed in the 2017 Quality Payment Program final rule (81 FR 77090), we want to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. As discussed in section III.H.3.h. of this proposed rule, we are proposing to limit the Medicare Part B claims submission type, and therefore, the Medicare Part B claims measures, to MIPS eligible clinicians in small practices. We refer readers to section III.H.3.h of this proposed rule for discussion of this proposal.

(bb) Submission Criteria for Groups Reporting CMS Web Interface Measures

While we are not proposing any changes to the established submission criteria for CMS Web Interface measures at § 414.1335(a)(2), beginning with the 2021 MIPS payment year, we are proposing to revise the terminology in which CMS Web Interface measures are referenced to align with the updated submission terminology as discussed in section III.H.3.h of this proposed rule. Therefore, we propose to revise § 414.1335(a)(2) from via the CMS Web Interface for groups consisting of 25 or more eligible clinicians only, to for CMS Web Interface measures.

In order to ensure that the collection of information is valuable to clinicians and worth the cost and burden of collecting information, and address the

challenge of fragmented reporting for multiple measures and submission options, we seek comment on expanding the CMS Web Interface option to groups with 16 or more eligible clinicians. Preliminary analysis has indicated that expanding the CMS Web Interface option to groups of 16 or more eligible clinicians will likely result in many of these new groups not being able fully satisfy measure case minimums on multiple CMS Web Interface measures. However, we can possibly mitigate this issue if we require smaller groups (with 16–24 eligible clinicians) to report on only a subset of the CMS Web Interface measures, such as the preventive care measures. We are interested in stakeholder feedback on the issue of expanding the CMS Web interface to groups of 16 or more, as well as other factors we should consider with such expansion.

As discussed in section III.F.1.c. of the Medicare Shared Savings Program portion of this proposed rule, changes proposed and finalized through rulemaking to the CMS Web Interface measures for MIPS would be applicable to ACO quality reporting under the Shared Savings Program. In Table Group D: Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years of the measures appendix, we are proposing to remove 6 measures from the CMS Web Interface in MIPS. If finalized, groups reporting CMS Web Interface measures for MIPS would not be responsible for reporting those removed measures. We refer readers to the quality measure appendix for additional details on the proposals related to changes in CMS Web Interface measures.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77116), the CMS Web Interface has a two-step attribution process that associates beneficiaries with TINs during the period in which performance is assessed (adopted from the Physician Value-based Payment Modifier (VM) program). The CAHPS for MIPS survey utilizes the same two-step attribution process as the CMS Web Interface. The CY 2017 Quality Payment Program final rule (81 FR 77116) noted that attribution would be conducted using the different identifiers in MIPS. For purposes of the CMS Web Interface and the CAHPS for MIPS survey, we clarify that attribution would be conducted at the TIN level.

(cc) Submission Criteria for Groups Electing To Report Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

While we are not proposing any changes to the established submission criteria for the CAHPS for MIPS Survey at § 414.1335(a)(3), beginning with the 2021 MIPS payment year, we are proposing to revise § 414.1335(a)(3) to clarify that for the CAHPS for MIPS survey, for the 12-month performance period, a group that wishes to voluntarily elect to participate in the CAHPS for MIPS survey measure must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measure data to us.

(B) Summary of Data Submission Criteria

We are not proposing any changes to the quality data submission criteria for the 2021 MIPS payment year in this proposed rule; however, as discussed in section III.H.3.h. of this proposed rule, we are proposing changes to existing and additional submission related terminology. Similarly, while we are not proposing changes to the data completeness criteria at § 414.1340, we are proposing to changes to existing and additional submission related terminology. For that reason, we are proposing to revise § 414.1340 to specify that MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or the eCQMs must submit data on at least 60 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2021; MIPS eligible clinicians and groups submitting quality measure data on the Medicare Part B claims measures must submit data on at least 60 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for the 2021 MIPS payment year; and groups submitting quality measures data on CMS Web Interface measures or the CAHPS for MIPS survey measure, must meet the data submission requirement on the sample of the Medicare Part B patients CMS provides. Below, we have included Tables 31 and 32 to clearly capture the data completeness requirements and submission criteria by collection type for individual clinicians and groups.

TABLE 31—SUMMARY OF DATA COMPLETENESS REQUIREMENTS AND PERFORMANCE PERIOD BY COLLECTION TYPE FOR THE 2020 AND 2021 MIPS PAYMENT YEARS

Collection type	Performance period	Data completeness
Medicare Part B claims measures ..	Jan 1–Dec 31 (or 90 days for selected measures).	60 percent of individual MIPS eligible clinician's, or group's (beginning with the 2021 MIPS payment year) Medicare Part B patients for the performance period.
Administrative claims measures	Jan 1–Dec 31	100 percent of individual MIPS eligible clinician's Medicare Part B patients for the performance period.
QCDR measures, MIPS CQMs, and eCQMs.	Jan 1–Dec 31 (or 90 days for selected measures).	60 percent of individual MIPS eligible clinician's, or group's patients across all payers for the performance period.
CMS Web Interface measures	Jan 1–Dec 31	Sampling requirements for the group's Medicare Part B patients: Populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries.
CAHPS for MIPS survey	Jan 1–Dec 31	Sampling requirements for the group's Medicare Part B patients.

TABLE 32—SUMMARY OF QUALITY DATA SUBMISSION CRITERIA FOR MIPS PAYMENT YEAR 2021 FOR INDIVIDUAL CLINICIANS AND GROUPS

Clinician type	Submission criteria	Measure collection types (or measure sets) available
Individual Clinicians	Report at least six measures including one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Individual MIPS eligible clinicians select their measures from the following collection types: Medicare Part B claims measures (individual clinicians in small practices only), MIPS CQMs, QCDR measures, eCQMs, or reports on one of the specialty measure sets if applicable.
Groups (non-CMS Web Interface).	Report at least six measures including one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Groups select their measures from the following collection types: Medicare Part B claims measures (small practices only), MIPS CQMs, QCDR measures, eCQMs, or the CAHPS for MIPS survey—or reports on one of the specialty measure sets if applicable. Groups of 16 or more clinicians who meet the case minimum of 200 will also be automatically scored on the administrative claims based all-cause hospital re-admission measure.
Groups (CMS Web Interface for group of at least 25 clinicians).	Report on all measures included in the CMS Web Interface collection type and optionally the CAHPS for MIPS survey. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Groups report on all measures included in the CMS Web Interface measures collection type and optionally the CAHPS for MIPS survey. Groups of 16 or more clinicians who meet the case minimum of 200 will also be automatically scored on the administrative claims based all-cause hospital re-admission measure.

(iv) Application of Facility-Based Measures

According to section 1848(q)(2)(C)(ii) of the Act, the Secretary may use measures for payment systems other than for physicians, such as measures used for inpatient hospitals, for purposes of the quality and cost performance categories. However, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. We refer readers to section III.H.3.i.(1)(d) of this proposed rule, Facility-Based Measures Scoring Option for the 2021 MIPS Payment Year for the Quality and Cost Performance Categories, for full discussion of facility-based measures

and scoring for the 2021 MIPS payment year.

(b) Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups Under the Annual List of Quality Measures Available for MIPS Assessment

(i) Background and Policies for the Call for Measures and Measure Selection Process

In the CY 2017 Quality Payment Program final rule (81 FR 77153), we established that we would categorize measures into the six NQS domains (patient safety, person-and caregiver-centered experience and outcomes, communication and care coordination, effective clinical care, community/population health, and efficiency and cost reduction). To streamline quality

measures, reduce regulatory burden, and promote innovation, we have developed and announced our Meaningful Measures Initiative.¹⁶ By identifying the highest priority areas for quality measurement and quality improvement, the Meaning Measures Initiative, identifies the core quality of care issues that advances our work to improve patient outcomes. Through subregulatory guidance, we will categorize quality measures by the 19 Meaningful Measure areas as identified on the Meaningful Measures Initiative website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient>

¹⁶ Link to Meaningful Measures web page on CMS site to be provided at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

Assessment-Instruments/Quality InitiativesGenInfo/MMF/General-info-Sub-Page.html. The categorization of quality measures by Meaningful Measure area would provide MIPS eligible clinicians and groups with guidance as to how each measure fits into the framework of the Meaningful Measure Initiative.

Furthermore, under § 414.1305, a high priority measure is defined as an outcome, appropriate use, patient safety, efficiency, patient experience or care coordination quality measure. Due to the immense impact of the opioid epidemic across the United States, we believe it is imperative to promote the measurement of opioid use and overuse, risks, monitoring, and education through quality reporting. For that reason, beginning with the 2019 performance period, we are proposing at § 414.1305 to amend the definition of a high priority measure, to include quality measures that relate to opioids and to further clarify the types of outcome measures that are considered high priority. Beginning with the 2021 MIPS payment year, we are proposing to define at § 414.1305 a high priority measure to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures would include intermediate-outcome and patient-reported outcome measures. We request comment on this proposal, specifically if stakeholders have suggestions on what aspects of opioids should be measured. For example, should we focus solely on opioid overuse?

Previously finalized MIPS quality measures can be found in the CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174) and in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). The new MIPS quality measures proposed for inclusion in MIPS for the 2019 performance period and future years are found in Table A of Appendix 1: Proposed MIPS Quality Measures of this proposed rule. The current specialty measure sets can be found in the CY 2018 Quality Payment Program final rule (82 FR 53976 through 54146). The proposed new and modified quality measure specialty sets can be found in Table B of Appendix 1: Proposed MIPS Quality Measures of this proposed rule, and include new proposed measures, previously finalized measures with proposed modifications, and previously finalized measures with no proposed modifications.

We note that modifications made to the specialty sets may include the

removal of certain previously finalized quality measures. Certain MIPS specialty sets have further defined subspecialty sets, each of which constitutes a separate specialty set. In instances where an individual MIPS eligible clinician or group reports on a specialty or subspecialty set, if the set has less than six measures, that is all the clinician is required to report. MIPS eligible clinicians are not required to report on the specialty measure sets, but they are suggested measures for specific specialties. Please note that the proposed specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 9, 2018,¹⁷ we announced that we would be accepting recommendations for potential new specialty measure sets for Year 3 of MIPS under the Quality Payment Program. These recommendations were based on the MIPS quality measures finalized in the CY 2018 Quality Payment Program final rule, and includes recommendations to add or remove the current MIPS quality measures from the specialty measure sets. All specialty measure set recommendations submitted for consideration were assessed to ensure that they meet the needs of the Quality Payment Program.

In the CY 2017 Quality Payment Program final rule (81 FR 77137), we finalized that substantive changes to MIPS quality measures, to include but are not limited to, measures that have had measure specification changes, measure title changes, or domain changes. MIPS quality measures with proposed substantive changes can be found in Table D of Appendix 1: Proposed MIPS Quality Measures of this proposed rule.

With regards to eQMs, in the 2015 EHR Incentive Program final rule, CMS required eligible clinicians, eligible hospitals, and critical access hospitals (CAHs) to use the most recent version of an eQCM for electronic reporting beginning in 2017 (80 FR 62893). We are proposing this policy for the end-to-end electronic reporting bonus under MIPS and encourage MIPS eligible clinicians to work with their EHR vendors to ensure they have the most recent version of the eQCM. CMS will not accept an older version of an eQCM as a submission for the MIPS program for

the quality performance category or the end-to-end electronic reporting bonus within that category. MIPS eligible clinicians and groups reporting on the quality performance category are required to use the most recent version of the eQCM specifications. The annual updates to the eQCM specifications and any applicable addenda are available on the electronic quality improvement (eCQI) Resource Center website at <https://ecqi.healthit.gov> for the applicable performance period. Furthermore, as discussed in section III.E. of this proposed rule, the Medicaid Promoting Interoperability Program intends to utilize eQCM measures as they are available in MIPS. We refer readers to section III.E. of this proposed rule for additional details and criteria on the Medicaid Promoting Interoperability Program.

In MIPS, there are a limited number of CMS Web Interface measures, we seek comment on building upon the CMS Web Interface submission type by expanding the core set of measures available for that submission type to include other specialty specific measures (such as surgery).

To provide clinicians with a more cohesive reporting experience, where they may focus on activities and measures that are meaningful to their scope of practice, we discuss the development of public health priority measurement sets that would include measures and activities across the quality, Promoting Interoperability, and improvement activities performance categories, focused on public health priorities such as fighting the opioid epidemic, in section III.H.3.h.(5), Promoting Interoperability. We refer readers to section III.H.3.h.(5) of this proposed rule for additional details on this concept.

(ii) Topped Out Measures

In the CY 2018 Quality Payment Program final rule (82 FR 53637 through 53640), we finalized the 4-year timeline to identify topped out measures, after which we may propose to remove the measures through future rulemaking. After a measure has been identified as topped out for 3 consecutive years through the benchmarks, we may propose to remove the measure through notice and comment rulemaking. Therefore, in the 4th year, if finalized through rulemaking, the measure would be removed and would no longer be available for reporting during the performance period. We refer readers to the 2018 MIPS Quality Benchmarks' file, that is located on the Quality Payment Program resource library (<https://www.cms.gov/Medicare/>

¹⁷ Listserv messaging was distributed through the Quality Payment Program listserv on January 9th, 2018, titled: "CMS is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2019 Program Year of Merit-based Incentive Payment System (MIPS)."

Quality-Payment-Program/Resource-Library/Resource-library.html) to determine which measure benchmarks are topped out for 2018 and would be subject to the cap if they are also topped out in the 2019 MIPS Quality Benchmarks' file. It should be noted that the final determination of which measure benchmarks are subject to the topped out cap would not be available until the 2019 MIPS Quality Benchmarks' file is released in late 2018.

We are proposing that once a measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors. We are concerned that topped out non-high priority process measures require data collection burden without added value for eligible clinicians and groups participating in MIPS. It is important to remove these types of measures, so that available measures provide meaningful value to clinicians collecting data, beneficiaries, and the program. However, we would also consider retaining the measure if there are compelling reasons as to why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to the Agency).

Since QCDR measures are not approved or removed from MIPS through the rulemaking timeline or cycle, we are proposing to exclude QCDR measures from the topped out timeline that was finalized in the CY 2018 Quality Payment Program final rule (82 FR 53640). When a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period. Because QCDRs have more flexibility to develop innovative measures, we believe there is limited value in maintaining topped out QCDR measures in MIPS.

(iii) Removal of Quality Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we discussed removal criteria for quality measures, including that a quality measure may be considered for removal if the Secretary determines that

the measure is no longer meaningful, such as measures that are topped out. Furthermore, if a measure steward is no longer able to maintain the quality measure, it would also be considered for removal.

We have previously communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. In the CY 2017 Quality Payment Program final rule (81 FR 77101), we explained that we believe that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality of care patients receive. In the CY 2018 Quality Payment Program quality measure set, 102 of the 275 quality measures are process measures that are not considered high priority. As discussed above, beginning with the 2021 MIPS payment year, we are proposing to define at § 414.1305 a high priority measure to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Because the removal of all non-high priority process measures would impact most specialty sets, nearly 94 percent, we believe incrementally removing non-high priority process measures through notice and comment rulemaking is appropriate.

Beginning with the 2019 performance period, we propose to implement an approach to incrementally remove process measures where prior to removal, considerations will be given to, but is not limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the measure addresses a priority area highlighted in the Measure Development Plan: <https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.html>.
- Whether the measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the measure is designated as high priority or not.
- Whether the measure has reached a topped out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, as described in the proposal in the above topped out measures section.

(iv) Categorizing Measures by Value

In outlining the various types of MIPS quality and QCDR measures available for reporting in the quality performance category, such as outcome, high-priority, composite, and process measures, we acknowledge that not all measures are created equal. For example, the value or information gained by reporting on certain process measures does not equate that which is collected on outcome measures. We seek to ensure that the collection and submission of data is valuable to clinicians and worth the cost and burden of collecting the information.

Based on this, we seek comment on implementing a system where measures are classified as a particular value (gold, silver or bronze) and points are awarded based on the value of the measure. For example, higher value measures that are considered "gold" standard, which could include outcome measures, composite measures, or measures that address agency priorities (such as opioids). The CAHPS for MIPS survey, which collects patient experience data, may also be considered a high value measure. Measures that are considered second tier, or at a "silver" standard would be measures that are considered process measures that are directly related to outcomes and have a good gap in performance (there is no high, unwavering performance) and demonstrate room for improvement; or topped out outcome measures. Lower value measures, such as standard of care process measures or topped out process measures would be considered "bronze" measures. We refer readers to section III.H.3.i. (1)(b)(xi) of this proposed rule for discussion on the assignment of value and scoring based on measure value.

(3) Cost Performance Category

For a description of the statutory basis and our existing policies for the cost performance category, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rule (81 FR 77162 through 77177, and 82 FR 53641 through 53648, respectively).

(a) Weight in the Final Score

In the CY 2018 Quality Payment Program final rule, we established that the weight of the cost performance category would be 10 percent of the final score for the 2020 MIPS payment year (82 FR 53643). We had previously finalized in the CY 2017 Quality Payment Program final rule at § 414.1350(b)(3) that beginning with the 2021 MIPS payment year, the cost performance category would be 30

percent of the final score, as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act (81 FR 77166). Section 51003(a)(1)(C) of the Bipartisan Budget Act of 2018, enacted on February 9, 2018, amended section 1848(q)(5)(E)(i)(II)(bb) of the Act such that for each of the second, third, fourth, and fifth years for which the MIPS applies to payments, not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the cost performance category score. Additionally, this provision shall not be construed as preventing the Secretary from adopting a 30 percent weight if the Secretary determines, based on information posted under section 1848(r)(2)(I) of the Act, that sufficient cost measures are ready for adoption for use under the cost performance category for the relevant performance period. Section 51003(a)(2) of the Bipartisan Budget Act of 2018 amended section 1848(r)(2) of the Act to add a new paragraph (I), which we discuss in section III.H.3.h.(3)(b)(i) of this proposed rule.

In light of these amendments, we propose at § 414.1350(d)(3) the cost performance category would make up 15 percent of a MIPS eligible clinician's final score for the 2021 MIPS payment year. As discussed in section III.H.3.h.(3)(b)(iv) of this proposed rule, we are proposing to codify the existing policies for the attribution of cost measures, which would result in redesignating § 414.1350(b) as § 414.1350(d). We propose to delete the existing text under § 414.1350(b)(3) and address the weight of the cost performance category for the MIPS payment years following 2021 in future rulemaking. We also propose a technical change to the text at § 414.1350(b) (redesignated as § 414.1350(d)) to state that the cost performance category weight will be as specified under redesignated § 414.1350(d), unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act.

We believe that measuring cost is an integral part of measuring value, and we believe that clinicians have a significant impact on the costs of patient care. However, we are proposing to only modestly increase the weight of the cost performance category for the 2021 MIPS payment year from the 2020 MIPS payment year because we recognize that cost measures are still relatively early in the process of development and that clinicians do not have the level of familiarity or understanding of cost measures that they do of comparable quality measures. As described in section III.H.3.h.(3)(b)(ii) of this proposed rule, we are proposing to add

8 episode-based measures to the cost performance category beginning with the 2019 MIPS performance period. This is a first step in developing a more robust and clinician-focused measurement of cost performance. We will continue to work on developing additional episode-based measures that we may consider proposing for the cost performance category in future years. Introducing more measures over time would allow for more clinicians to be measured in this performance category. It would also allow time for more outreach to clinicians to better educate them on the cost measures. We considered maintaining the weight of the cost performance category at 10 percent for the 2021 MIPS payment year as we recognize that clinicians are still learning about the cost performance category and being introduced to new measures. We invite comment on whether we should consider an alternative weight for the 2021 MIPS payment year.

In accordance with section 1848(q)(5)(E)(i)(II)(bb) of the Act, we will continue to evaluate whether sufficient cost measures are ready for adoption under the cost performance category and move towards the goal of increasing the weight to 30 percent of the final score. To provide for a smooth transition, we anticipate that we would increase the weight of the cost performance category by 5 percentage points each year until we reach the required 30 percent weight for the 2024 MIPS payment year. We invite comments on this approach to the weight of the cost performance category for the 2022 and 2023 MIPS payment years, considering our flexibility in setting the weight between 10 percent and 30 percent of the final score, the availability of cost measures, and our desire to ensure a smooth transition to a 30 percent weight for the cost performance category.

(b) Cost Criteria

(i) Background

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. In the CY 2018 Quality Payment Program final rule, we established two cost measures (total per capita cost measure and Medicare spending per beneficiary (MSPB) measure) for the 2018 MIPS performance period and future performance periods (82 FR 53644). These measures were previously established for the 2017 MIPS performance period (81 FR 77168). We

will continue to evaluate cost measures that are included in MIPS on a regular basis and anticipate that measures could be added or removed through rulemaking as measure development continues. In general, we expect to evaluate cost measures according to the measure reevaluation and maintenance processes outlined in the "Blueprint for the CMS Measures Management System" (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf>). As described in section 2 of the Blueprint for the CMS Measures Management System Version 13.0, we will conduct annual evaluations to review the continued accuracy of the measure specifications. Annual updates ensure that the procedure, diagnostic, and other codes used in the measure account for updates to coding systems over time. To the extent that these updates would constitute a substantive change to a measure, we would ensure the changes are proposed for adoption through rulemaking. We will also comprehensively reevaluate the measures every 3 years to ensure that they continue to meet measure priorities. As a part of this comprehensive reevaluation, we will gather information through environmental scans and literature reviews of recent studies and new clinical guidelines that may inform potential refinements. We will also analyze measure performance rates and re-assess the reliability and validity of the measures. Throughout these reevaluation efforts, we will summarize and consider all stakeholder feedback received on the measure specifications during the implementation process, and may seek input through public comment periods. In addition, the measure development contractor may acquire individual input on measures by convening Technical Expert Panels (TEPs) and clinical subcommittees. Aside from these regular measure reevaluations, there may be ad-hoc reviews of the measures if new evidence comes to light which indicates that significant revisions may be required.

We will also continue to update the specifications to address changes in coding, risk adjustment, and other factors. The process for updating measure specifications will take place through ongoing maintenance and evaluation, during which we expect to continue seeking stakeholder input. As we noted above, any substantive changes to a measure would be proposed for adoption in future years through notice and comment

rulemaking. We appreciate the feedback that we have received so far throughout the measure development process and believe that stakeholders will continue to provide feedback to the measure development contractor on episode-based cost measures by submitting written comments during public comment opportunities, by participating in the clinical subcommittees convened by the measure development contractor, or by attending education and outreach events. We will take all comments and feedback into consideration as part of the ongoing measure evaluation process.

As we noted in the CY 2017 Quality Payment Program final rule (81 FR 77137) regarding quality measures, which we believe would also apply for cost measures, some updates may incorporate changes that would not substantively change the intent of the measure. Examples of such changes may include updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. While we address such changes on a case-by-case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures. As described in section 3 of the Blueprint for the CMS Measures Management System Version 13.0, if substantive changes to these measures become necessary, we expect to follow the pre-rulemaking process for new measures, including resubmission to the Measures Under Consideration (MUC) list and consideration by the Measure Applications Partnership (MAP). The MAP provides an additional opportunity for an interdisciplinary group of stakeholders to provide feedback on whether they believe the measures under consideration are attributable and applicable to clinicians. The MAP also reviews measures for clinician level feasibility, reliability, and validity. They also consider whether the measures are scientifically acceptable, and reflect current clinical guidelines.

Section 51003(a)(2) of the Bipartisan Budget Act of 2018 amended section 1848(r)(2) of the Act to add a new paragraph (I) requiring the Secretary to post on the CMS website information on cost measures in use under MIPS, cost measures under development and the time-frame for such development, potential future cost measure topics, a description of stakeholder engagement, and the percent of expenditures under Medicare Part A and Part B that are covered by cost measures. This information shall be posted no later than December 31 of each year

beginning with 2018. We expect this posting will provide a list of the cost measures established for the cost performance category for the current performance period (for example, the posting in 2018 would include a list of the measures for the 2018 MIPS performance period), as well as a list of any cost measures that may be proposed for a future performance period through rulemaking. We will provide hyperlinks to the measure specifications documents, and include the percent of Medicare Part A and Part B expenditures that are covered by these cost measures. The posting will also include a list and description of the measures under development at that time. We intend to summarize the timeline for measure development, including the stakeholder engagement activities undertaken, which may include a TEP, clinical subcommittees, field testing, and education and outreach activities, such as national provider calls and listening sessions. Finally, the posting will provide an overview of potential future topics in cost measure development, such as any clinical areas in which measures may be developed in the future.

(ii) Episode-Based Measures Proposed for the 2019 and Future Performance Periods

Episode-based measures differ from the total per capita cost measure and MSPB measure because episode-based measure specifications only include items and services that are related to the episode of care for a clinical condition or procedure (as defined by procedure and diagnosis codes), as opposed to including all services that are provided to a patient over a given timeframe.

We discussed our progress in the development of episode-based measures in the CY 2018 Quality Payment Program proposed rule (82 FR 30049 through 30050) and received significant positive feedback on the process used to develop the measures as well as the measures' clinical focus that was informed by expert opinion (82 FR 53644 through 53646). The specific measures selected for the initial round of field testing were included based on the volume of beneficiaries impacted by the condition or procedure, the share of cost to Medicare impacted by the condition or procedure, the number of clinicians/clinician groups attributed, and the potential for alignment with existing quality measures.

We have developed episode-based measures to represent the cost to Medicare for the items and services furnished to a patient during an episode of care ("episode"). Episode-based

measures are developed to let attributed clinicians know the cost of the care clinically related to their initial treatment of a patient and provided during the episode's timeframe. Specifically, we define cost based on the allowed amounts on Medicare claims, which include both Medicare payments and beneficiary deductible and coinsurance amounts. Episode-based measures are calculated using Medicare Parts A and B fee-for-service claims data and are based on episode groups.

Episode groups:

- Represent a clinically cohesive set of medical services rendered to treat a given medical condition.
- Aggregate all items and services provided for a defined patient cohort to assess the total cost of care.
- Are defined around treatment for a condition (acute or chronic) or performance of a procedure.

Items and services in the episode group could be treatment services, diagnostic services, and ancillary items and services directly related to treatment (such as anesthesia for a surgical procedure). They could also be items and services that occur after the initial treatment period that may be furnished to patients as follow-up care or to treat complications resulting from the treatment. An episode is a specific instance of an episode group for a specific patient and clinician. For example, in a given year, a clinician might be attributed 20 episodes (instances of the episode group) from the episode group for heart failure. In section III.H.3.h.(3)(b)(iv) of this proposed rule, we discuss the attribution rules for cost measures.

After episodes are attributed to one or more clinicians, items and services may be included in the episode costs if they are furnished within a patient's episode window. Items and services will be included if they are the trigger event for the episode or if a service assignment rule identifies them as a clinically related item or service during the episode. The detailed specifications for these measures, which include information about the service assignment rule, can be reviewed at qpp.cms.gov.

To ensure a more accurate comparison of cost across clinicians, episode costs are payment standardized and risk adjusted. Payment standardization adjusts the allowed amount for an item or service to facilitate cost comparisons and limit observed differences in costs to those that may result from health care delivery choices. Payment standardized costs remove any Medicare payment differences due to adjustments for

geographic differences in wage levels or policy-driven payment adjustments such as those for teaching hospitals. Risk adjustment accounts for patient characteristics that can influence spending and are outside of clinician control. For example, for the elective outpatient PCI episode-based measure, the risk adjustment model may account for a patient's history of heart failure.

The measure development contractor has continued to seek extensive stakeholder feedback on the development of episode-based measures, building on the processes outlined in the CY 2018 Quality Payment Program final rule (82 FR 53644). These processes included convening a TEP and clinical subcommittees to solicit expert and clinical input for measure development, conducting national field testing on the episode-based cost measures developed, and seeking input from clinicians and stakeholders through engagement activities. Seven clinical subcommittees were convened through an open call for nominations between March 17, 2017 and April 24, 2017, composed of nearly 150 clinicians affiliated with almost 100 specialty societies. These subcommittees met at an in-person meeting and through webinars from May 2017 to January 2018 to select an episode group or groups to develop and provide detailed clinical input on each component of episode-based cost measures. These components included episode triggers and windows, item and service assignment, exclusions, attribution methodology, and risk adjustment variables.

As described in the CY 2018 Quality Payment Program final rule (82 FR 53645), we provided an initial opportunity for clinicians to review their performance based on the new episode-based measures developed by the clinical subcommittees in the fall of 2017 through national field testing. During the period of October 16, 2017

to November 20, 2017, solo practitioners and clinician groups were able to access field test reports about their cost measure performance on the CMS Enterprise Portal if they were attributed at least 10 episodes for at least one of these eight measures during the measurement period of June 1, 2016 to May 31, 2017. In addition to the field test reports, stakeholders could review a range of materials about the new episode-based cost measures, including a fact sheet, frequently asked questions (FAQ) document, a mock field test report, and draft measure specifications for each of the 8 new episode-based measures (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Episode-based-cost-measures-field-test-files.zip>).

During field testing, we sought feedback from stakeholders on the draft measure specifications, feedback report format, and supplemental documentation through an online form. We received over 200 responses, including 53 comment letters, during the field test feedback period. We shared the feedback on the draft measure specifications with the clinical subcommittees who considered it in providing input on measure refinements after the end of field testing. A field testing feedback summary report is publicly available at qpp.cms.gov.

To engage clinicians and stakeholders, we conducted extensive outreach activities including hosting National Provider Calls (NPCs) to provide information about the measure development process and field test reports, and to give stakeholders the opportunity to ask questions.

The new episode-based measures developed by the clinical subcommittees were considered by the NQF-convened MAP, and were all conditionally supported by the MAP, with the recommendation of obtaining

NQF endorsement. We intend to submit these episode-based measures to NQF for endorsement in the future. The MAP provides an opportunity for an interdisciplinary group of stakeholders to provide input on whether the measures under consideration are attributable and applicable to clinicians. The MAP also reviews measures for clinician level feasibility, reliability, and validity. Following the successful field testing and review through the MAP process, we propose to add 8 episode-based measures listed in Table 33 as cost measures for the 2019 MIPS performance period and future performance periods.

The attribution methodology for these measures is discussed in section III.H.3.h.(3)(b)(iv)(B) of this proposed rule. The detailed specifications for these measures can be reviewed at qpp.cms.gov. These specifications documents consist of (i) a methods document that outlines the methodology for constructing the measures, and (ii) a measure codes list file that contains the medical codes used in that methodology. First, the methods document provides a high-level overview of the measure development process, including discussion of the detailed clinical input obtained at each step, and details about the components of episode-based cost measures: Defining an episode group; assigning costs to the episode group; attributing the episode group; risk adjusting episode group costs; and aligning cost with quality. The methods document also contains the detailed measure methodology that describes each logic step involved in constructing the episode groups and calculating the cost measure. Second, the measure codes list file contains the codes used in the specifications, including the episode triggers, exclusions, episode sub-groups, assigned items and services, and risk adjusters.

TABLE 33—EPISODE-BASED MEASURES PROPOSED FOR THE 2019 MIPS PERFORMANCE PERIOD AND FUTURE PERFORMANCE PERIODS

Measure topic	Measure type
Elective Outpatient Percutaneous Coronary Intervention (PCI)	Procedural.
Knee Arthroplasty	Procedural.
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	Procedural.
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	Procedural.
Screening/Surveillance Colonoscopy	Procedural.
Intracranial Hemorrhage or Cerebral Infarction	Acute inpatient medical condition.
Simple Pneumonia with Hospitalization	Acute inpatient medical condition.
ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)	Acute inpatient medical condition.

(iii) Reliability

In the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77170), we finalized a reliability threshold of 0.4 for measures in the cost performance category. We seek to ensure that MIPS eligible clinicians are measured reliably. In the CY 2017 Quality Payment Program final rule, we finalized a case minimum of 20 for the episode-based measures specified for the 2017 MIPS performance period (81 FR 77175). We examined the reliability of the proposed 8 episode-based measures listed in Table 33 at various case minimums and found that all of these measures meet the reliability

threshold of 0.4 for the majority of clinicians and groups at a case minimum of 10 episodes for procedural episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures. Furthermore, these case minimums would balance the goal of increased reliability with the goal of adopting cost measures that are applicable to a larger set of clinicians and clinician groups. Our analysis indicated that the case minimum for procedural episode-based measures could be lower than that of acute inpatient medical condition episode-based measures while still ensuring reliable measures.

Table 34 presents the percentage of TINs and TIN/NPIs with 0.4 or higher reliability, as well as the mean reliability for the subset of TINs and TIN/NPIs who met the proposed case minimums of 10 episodes for procedural episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures for each of the proposed episode-based measures. Each row in this table provides the percentage of TINs and TIN/NPIs who had reliability of 0.4 or higher among all the TINs and TIN/NPIs who met the case minimum for that measure during the study period (6/1/2016 to 5/31/2017).

TABLE 34—PERCENTAGE OF TINs AND TIN/NPIs WITH 0.4 OR HIGHER RELIABILITY FROM JUNE 1, 2016 TO MAY 31, 2017 AT PROPOSED CASE MINIMUMS

Measure name	Percentage TINs with 0.4 or higher reliability	Mean reliability for TINs	Percentage TIN/NPIs with 0.4 or higher reliability	Mean reliability for TIN/NPIs
Elective Outpatient Percutaneous Coronary Intervention (PCI)	100.0	0.73	84.1	0.53
Knee Arthroplasty	100.0	0.87	100.0	0.81
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	100.0	0.74	100.0	0.64
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	100.0	0.95	100.0	0.94
Screening/Surveillance Colonoscopy	100.0	0.96	100.0	0.93
Intracranial Hemorrhage or Cerebral Infarction	100.0	0.70	74.9	0.48
Simple Pneumonia with Hospitalization	100.0	0.64	31.8	0.40
ST-Elevation Myocardial Infarction (STEMI) with PCI	100.0	0.59	100.0	0.59

Based on this analysis, we propose at § 414.1350(c)(4) and (5) a case minimum of 10 episodes for the procedural episode-based measures and 20 episodes for the acute inpatient medical condition episode-based measures that we have proposed beginning with the 2019 MIPS performance period. These case minimums would ensure that the measures meet the reliability threshold for groups and individual clinicians. We believe that the proposed case minimums for these procedural and acute inpatient medical condition episode-based measures would achieve a balance between several important considerations. In order to help clinicians become familiar with the episode-based measures as a robust and clinician-focused form of cost measurement, we want to provide as many clinicians as possible the opportunity to receive information about their performance on reliable measures. This is consistent with the stakeholder feedback that we have received throughout the measure development process. We believe that calculating episode-based measures with these case minimums would accurately and reliably measure the performance of a large number of clinicians and clinician group practices.

We recognize that the percentage of TIN/NPIs with 0.4 or greater reliability for the Simple Pneumonia with Hospitalization measure, while still meeting our reliability threshold, is somewhat lower than that of the other proposed acute inpatient medical condition episode-based measures, as well as all of the proposed procedural episode-based measures. For this reason, we considered an alternative case minimum of 30 for both TIN/NPIs and TINs for this measure. At this case minimum, 100 percent of TIN/NPIs would have 0.4 or greater reliability and the mean reliability would increase to 0.49 for TIN/NPIs and 0.70 for TINs. However, the number of TINs and TIN/NPIs that would meet the case minimum for this important measure would decrease by 29 percent for TINs and by 84 percent for TIN/NPIs. We invite comments on this alternative case minimum for TIN/NPIs and TINs for the Simple Pneumonia with Hospitalization episode-based measure.

We previously finalized a case minimum of 35 for the MSPB measure (81 FR 77171), 20 for the total per capita cost measure (81 FR 77170), and 20 for the episode-based measures specified for the 2017 MIPS performance period

(81 FR 77175). We propose to codify these final policies under § 414.1350(c).

In general, higher case minimums increase reliability, but also decrease the number of clinicians who are measured. We aim to measure as many clinicians as possible in the cost performance category. Some clinicians or smaller groups may never see enough patients in a single year to meet the case minimum for a specific episode-based measure. For this reason, we seek comment on whether we should consider expanding the performance period for the cost performance category measures from a single year to 2 or more years in future rulemaking. We believe this would allow us to more reliably measure a larger number of clinicians. However, we are also concerned that expanding the performance period would increase the time between the measurement of performance and the application of the MIPS payment adjustment. In addition, it would take a longer period of time for us to introduce new cost measures as we would expect to adopt them through rulemaking prior to the beginning of the performance period.

(iv) Attribution

(A) Attribution Methodology for Cost Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77168 through 77169; 77174 through 77176), we adopted final policies concerning the attribution methodologies for the total per capita cost measure, the MSPB measure, and the episode-based measures specified for the 2017 MIPS performance period in addition to an attribution methodology for individual clinicians and groups. We propose to codify these final policies under § 414.1350(b).

(B) Attribution Rules for the Proposed Episode-Based Measures

In section III.H.3.h.(3)(b)(ii) of this proposed rule, we propose to add 8 episode-based measures as cost measures for the 2019 MIPS performance period and future performance periods, which can be categorized into two types of episode groups: Acute inpatient medical condition episode groups, and procedural episode groups. These measures only include items and services that are related to the episode of care for a clinical condition or procedure (as defined by procedure and diagnosis codes), as opposed to including all services that are provided to a patient over a given period of time. The attribution methodology would be the same for all of the measures within each type of episode groups—acute inpatient medical condition episode groups and procedural episode groups. Our proposed approach to attribution would ensure that the episode-based measures reflect the roles of the individuals and groups in providing care to patients.

For acute inpatient medical condition episode groups specified beginning in the 2019 performance period, we propose at § 414.1350(b)(6) to attribute episodes to each MIPS eligible clinician who bills inpatient evaluation and management (E&M) claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization. A trigger inpatient hospitalization is a hospitalization with a particular MS-DRG identifying the episode group. These MS-DRGs, and any supplementary trigger rules, are identified in the measure specifications posted at qpp.cms.gov. The measure score for an individual clinician (TIN/NPI) is based on all of the episodes attributed to the individual. The measure score for a group (TIN) is based on all of the episodes attributed to a

TIN/NPI in the given TIN. If a single episode is attributed to multiple TIN/NPIs in a single TIN, the episode is only counted once in the TIN's measure score. We believe that establishing a 30 percent threshold for the TIN would ensure that the clinician group is collectively measured across all of its clinicians who are likely responsible for the oversight of care for the patient during the trigger hospitalization.

This proposed attribution approach differs from the attribution approach previously established for episode-based measures for acute inpatient medical conditions specified for the 2017 performance period in the CY 2017 Quality Payment Program final rule (81 FR 77174 through 77175). The previous approach attributed episodes to TIN/NPIs who individually exceed the 30 percent E&M threshold, while excluding all episodes where no TIN/NPI exceeds the 30 percent threshold. Throughout the measure development process, stakeholders have discussed the team-based nature of acute care, in which multiple clinicians share management of a patient during a hospital stay. The previous approach outlined in the CY 2017 Quality Payment Program final rule (81 FR 77174 through 77175) does not capture patients' episodes when a group collaborates to manage a patient but no individual clinician exceeds the 30 percent threshold. Based upon stakeholder feedback, our proposed approach emphasizes team-based care and expands the measures' coverage of clinicians, patients, and cost.

To illustrate the proposed attribution rules for acute inpatient medical condition episode groups, we are providing an example where 3 MIPS eligible clinicians are part of the same TIN. The TIN bills 50 percent of total inpatient E&M claim lines during an inpatient hospitalization. Clinician A and B each bill 3 inpatient E&M claim lines under the TIN, and Clinician C bills none under the TIN. If MIPS eligible clinicians under this TIN are scored as individual TIN/NPIs, this episode would be attributed to Clinicians A and B, but not Clinician C. The episode would be used to calculate Clinician A's measure score and Clinician B's measure score, but not Clinician C's. The episode would count towards the individual 20 episode case minimums for both Clinicians A and B. If this TIN is instead scored as a group, the episode would be included in the calculation of the TIN's measure score because it has exceeded the 30 percent inpatient E&M threshold. This episode would count towards the TIN's 20 episode case minimum. We note that this episode would only be counted

once towards the TIN's score, even though 2 clinicians under the TIN exceeded the 30 percent threshold. The previous attribution approach outlined in the CY 2017 Quality Payment Program final rule (81 FR 77174 through 77175) would discard this episode altogether. Specifically, it would not attribute this episode to Clinician A, B, or C, in the above example and the episode would not be included in these clinicians' measures or their TIN's measure.

For procedural episode groups specified beginning in the 2019 MIPS performance period, we propose at § 414.1350(b)(7) to attribute episodes to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes. These trigger services are identified in the measure specifications posted at qpp.cms.gov. The measure score for an individual clinician (TIN/NPI) is based on all of the episodes attributed to the individual. The measure score for a group (TIN) is based on all of the episodes attributed to a TIN/NPI in the given TIN. If a single episode is attributed to multiple TIN/NPIs in a single TIN, the episode is only counted once in the TIN's measure score. We believe this approach best identifies the clinician(s) responsible for the patient's care. This attribution method is similar to that used for procedural episode-based measures in the 2017 MIPS performance period but more clearly defines that the services must be provided during the episode and how we would address instances in which two NPIs in the same TIN provided a trigger service.

(4) Improvement Activities Performance Category

(a) Background

In CY 2017 Quality Payment Program final rule (81 FR 77179 through 77180), we codified at § 414.1355 that the improvement activities performance category would account for 15 percent of the final score. We refer readers to section III.H.3.i.(1)(e) of this proposed rule where we are proposing to modify § 414.1355 to provide further technical clarifications. In addition, in the CY 2018 Quality Payment Program final rule (82 FR 53649), we codified at § 414.1380(b)(3)(iv) that the term "recognized" be accepted as equivalent to the term "certified" when referring to the requirements for a patient-centered medical home to receive full credit for the improvement activities performance category for MIPS. We also finalized at § 414.1380(b)(3)(x) that for the 2020 MIPS payment year and future years, to

receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice (82 FR 53655). We refer readers to section III.H.3.i.(1)(e)(i)(E) of this proposed rule for details on our proposals regarding patient-centered medical homes.

In the CY 2017 Quality Payment Program final rule (81 FR 77539), we codified the definition of improvement activities at § 414.1305 to mean an activity that relevant MIPS eligible clinicians, organizations, and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. Further, in that final rule (81 FR 77190), we codified at § 414.1365 that the improvement activities performance category would include the subcategories of activities provided at section 1848(q)(2)(B)(iii) of the Act. We also codified subcategories for improvement activities at § 414.1365 (81 FR 77190).

We also previously codified in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77180 and 82 FR 53651, respectively) data submission criteria for the improvement activities performance category at § 414.1360(a)(1). In addition, we established exceptions for: Small practices; practices located in rural areas; practices located in geographic HPSAs; non-patient facing individual MIPS eligible clinicians or groups; and individual MIPS eligible clinicians and groups that participate in a MIPS APM or a patient-centered medical home submitting in MIPS (81 FR 77185, 77188). Specifically, we codified at § 414.1380(b)(3)(vii) that non-patient facing MIPS eligible clinicians and groups, small practices, and practices located in rural areas and geographic HPSAs receive full credit for the improvement activities performance category by selecting one high-weighted improvement activity or two medium-weighted improvement activities; such practices receive half credit for the improvement activities performance category by selecting one medium-weighted improvement activity (81 FR 77185). We refer readers to section III.H.3.i.(1)(e)(i)(B) of this proposed rule for our proposals related to that provision. In addition, we specified at § 414.1305 that rural areas refers to ZIP codes designated as rural, using the most recent HRSA Area Health Resource File data set available (81 FR 77188, 82

FR 53582). Lastly, we finalized the meaning of Health Professional Shortage Areas (HPSA) at § 414.1305 to mean areas as designated under section 332(a)(1)(A) of the Public Health Service Act (81 FR 77188). In the CY 2018 Quality Payment Program final rule (82 FR 53581), we modified the definition of small practices at § 414.1305 to mean practices consisting of 15 or fewer eligible clinicians.

In this proposed rule, we request comments on our proposals to: (1) Revise § 414.1360(a)(1) to more accurately describe the data submission criteria; (2) delete § 414.1365 and move improvement activities subcategories to § 414.1355(c); (3) update the criteria considered for nominating new improvement activities; (4) modify the Annual Call for Activities timeline for the CY 2019 performance period and future years; (5) add 6 new improvement activities for the CY 2019 performance period and future years; (6) modify 5 existing improvement activities for the CY 2019 performance period and future years; and (7) remove 1 existing improvement activity for the CY 2019 performance period and future years. In addition, we also request comments on our proposals with respect to the CMS Study on Factors Associated with Reporting Quality Measures for the CY 2019 performance period and future years the following proposals: (1) Change the title of the study to “CMS Study on Factors Associated with Reporting Quality Measures;” (2) increase the sample size to a minimum of 200 participants; (3) limit the focus group requirement to a subset of the 200 participants; and (4) require that at least one of the minimum of three required measures be a high priority measure. We are also making clarifications to: (1) Considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities.

These topics are discussed in more detail below.

(b) Submission Criteria

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77181) for submission mechanism policies we finalized and codified for the transition year of MIPS. In the CY 2018 Quality Payment Program final rule (82 FR 53651), we continued these policies for future years. Specifically, we finalized that for MIPS Year 2 and future years, MIPS eligible clinicians or groups must submit data on MIPS improvement activities in one of the following manners: Qualified registries; EHR submission mechanisms; QCDR;

CMS Web Interface; or attestation. Additionally, we finalized that for activities that are performed for at least a continuous 90-days during the performance period, MIPS eligible clinicians must submit a yes response for activities within the improvement activities inventory. In addition, in the case where an individual MIPS eligible clinician or group is using a health IT vendor, QCDR, or qualified registry for their data submission, we finalized that the MIPS eligible clinician or group must certify all improvement activities were performed and the health IT vendor, QCDR, or qualified registry would submit on their behalf (82 FR 53650 through 53651). We also updated § 414.1360 to reflect those changes (82 FR 53651).

We refer readers to section III.H.3.h.(1) of this proposed rule, MIPS Performance Category Measures and Activities, where we discuss our proposals to update the data submission process for MIPS eligible clinicians, groups and third party intermediaries, by updating our terminology. We also refer readers to proposed changes to § 414.1325 for Data submission requirements. We are proposing those changes to more closely align with the actual submission experience users have. In alignment with those proposals, we are requesting comments on our proposal to revise § 414.1360(a)(1) to more accurately reflect the data submission process for the improvement activities performance category. In particular, we are proposing that instead of “via qualified registries; EHR submission mechanisms; QCDR, CMS Web Interface; or attestation,” as currently stated, we are revising the first sentence to state that data would be submitted “via direct, login and upload, and login and attest” as discussed in section III.H.3.h.(1)(b) of this proposed rule.

In addition, we are proposing to add further additions to § 414.1360(a)(1) to include paragraph (i). In § 414.1360(a)(1), we are proposing to specify, submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

(c) Subcategories

In the CY 2017 Quality Payment Program final rule (81 FR 77190), we finalized at § 414.1365 that the improvement activities performance category includes the subcategories of activities provided at section 1848(q)(2)(B)(iii) of the Act. It has since come to our attention that it is unnecessary to have a separate

regulation text included under § 414.1365 since the subcategories are not a component of the scoring calculations. Therefore, we are proposing to delete § 414.1365 and move the same improvement activities subcategories to § 414.1355(c). We reiterate that we are not proposing any changes to the subcategories themselves. These subcategories are:

- Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.

- Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a QCDR.

- Care coordination, such as timely communication of test results, timely exchange of clinical information to patients or other clinicians, and use of remote monitoring or telehealth.

- Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision making mechanisms.

- Patient safety and practice assessment, such as through the use of clinical or surgical checklists and practice assessments related to maintaining certification.

- Participation in an APM.

- Achieving health equity, such as for MIPS eligible clinicians that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, people living in rural areas, and people in geographic HPSAs.

- Emergency preparedness and response, such as measuring MIPS eligible clinician participation in the Medical Reserve Corps, measuring registration in the Emergency System for Advance Registration of Volunteer Health Professionals, measuring relevant reserve and active duty uniformed services MIPS eligible clinician activities, and measuring MIPS eligible clinician volunteer participation in domestic or international humanitarian medical relief work.

- Integrated behavioral and mental health, such as measuring or evaluating such practices as: Co-location of behavioral health and primary care services; shared/integrated behavioral health and primary care records; cross training of MIPS eligible clinicians, and integrating behavioral health with primary care to address substance use disorders or other behavioral health

conditions, as well as integrating mental health with primary care.

(d) Improvement Activities Inventory

In this section of this proposed rule, we are proposing to: (1) Adopt one new criterion and remove one existing criterion for nominating new improvement activities beginning with the CY 2019 performance period and future years; (2) modify the timeframe for the Annual Call for Activities; (3) add 6 new improvement activities for the CY 2019 performance period and future years; (4) modify 5 existing improvement activities for the CY 2019 performance period and future years; and (5) remove 1 existing improvement activity for the CY 2019 performance period and future years. We are also making clarifications to: (1) Considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities.

(i) Annual Call for Activities

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial Improvement Activities Inventory and took several steps to ensure it was inclusive of activities in line with statutory and program requirements. For Year 2, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive Improvement Activities Inventory for the Quality Payment Program Year 2 and future years through subregulatory guidance (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf). In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for Year 3 and future years, we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the Improvement Activities Inventory, including information required to submit a nomination form similar to the one we utilized for Year 2 (82 FR 53656 through 53659). It is important to note that in order to submit a request for a new activity or a modification to an existing improvement activity the stakeholder must submit a nomination form found at www.qpp.cms.gov during the Annual Call for Improvement Activities.

(A) Criteria for Nominating New Improvement Activities

In this proposed rule, we are proposing to add one new criterion and remove a previously adopted criterion from the improvement activities nomination criteria. We are also clarifying our considerations in selecting improvement activities.

(aa) Currently Adopted Criteria

In the CY 2017 Quality Payment final rule (81 FR 77190 through 77195), we discussed guidelines for the selection of improvement activities. In the CY 2018 Quality Payment Program final rule, we formalized the Annual Call for Activities process for Year 3 and future years and added additional criteria; stakeholders would apply one or more of the below criteria when submitting nominations for improvement activities (82 FR 53660):

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcome;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family's point of view;
- Support the patient's family or personal caregiver;
- Activities that may be considered for an advancing care information bonus;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes; or
- CMS is able to validate the activity.

(bb) Proposed New Criteria

We believe it is important to place attention on public health emergencies, such as the opioid epidemic, when considering improvement activities for inclusion in the Inventory, because their inclusion raises awareness for clinicians about the urgency of the situation and to promote clinician adoption of best practices to combat those public health emergencies. A list of the public health emergency declarations is available at

<https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx>.

Therefore, in this proposed rule, we are proposing to adopt an additional criterion entitled “Include a public health emergency as determined by the Secretary” to the criteria for nominating new improvement activities beginning with the CY 2019 performance period and future years. We invite public comment on our proposal.

(cc) Proposed Removal of One Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77202 through 77209), we adopted a policy to award a bonus to the Promoting Interoperability performance category score for MIPS eligible clinicians who use CEHRT to complete certain activities in the improvement activities performance category. We included a designation column in the Improvement Activities Inventory at Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77817) that indicated which activities qualified for the Promoting Interoperability (formerly Advancing Care Information) bonus codified at § 414.1380(b)(4)(i)(D).

In section III.H.3.h.(5)(d)(ii) of this proposed rule, under the Promoting Interoperability performance category, we are proposing a new approach for scoring that moves away from the base, performance, and bonus score methodology currently established. This new approach would remove the availability of a bonus score for attesting to completing one or more specified improvement activities using CEHRT beginning with the CY 2019 performance period and future years. If this policy is finalized, then we do not believe the criterion for selecting improvement activities for inclusion in the program entitled “Activities that may be considered for an advancing care information bonus” remains relevant. Therefore, we are proposing to remove the criterion for selecting improvement activities for inclusion in the program entitled “Activities that may be considered for an advancing care information bonus” beginning with the CY 2019 performance period and future years. We note that this proposal is being made in alignment with and contingent upon those in section III.H.3.h.(5)(d)(ii) of the proposed rule. If those proposals are not finalized, this proposal would also not be finalized.

If our proposals to add one criterion and remove one criterion are adopted as proposed, the new list of criteria for nominating new improvement activities for the CY 2019 performance period and future years would be as follows:

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcome;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family’s point of view;
- Support the patient’s family or personal caregiver;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
- Include a public health emergency as determined by the Secretary; or
- CMS is able to validate the activity.

(B) Considerations in Selecting Improvement Activities

As noted in the CY 2017 Quality Payment final rule, we intend to use the criteria for nominating new improvement activities in selecting improvement activities for inclusion in the program (82 FR 53659). However, we clarify here that those criteria are but one factor in determining which improvement activities we ultimately propose. For example, we also generally take into consideration other factors, such as whether the nominated improvement activity uses publically available products or techniques (that is, does not contain proprietary products or information limiting an activity) or whether the nominated improvement activity duplicates any currently adopted activity.

(C) Weighting of Improvement Activities

Given stakeholder feedback requesting additional transparency regarding the weighting of improvement activities (82 FR 53657), in this proposed rule, we are summarizing considerations we have previously used to assign weights to improvement activities included in the Improvement Activities Inventory (see Appendix 2: Improvement Activities, Tables A and B). We are also making a few clarifications and seeking comment for future weighting considerations. These topics are discussed in more detail below.

(aa) Summary of Past Considerations

In the CY 2017 Quality Payment Program final rule (81 FR 77191), we explained that to define the criteria and establish weighting for each activity, we engage multiple stakeholder groups, including the Centers for Disease Control, Health Resources and Services Administration, Office of the National Coordinator for Health Information Technology, SAMHSA, Agency for Healthcare Research and Quality, Food and Drug Administration, the Department of Veterans Affairs, and several clinical specialty groups, small and rural practices and non-patient facing clinicians. Activities were proposed to be weighted as high based on the extent to which they align with activities that support the patient-centered medical home, since that is the standard under section 1848(q)(5)(C)(i) of the Act for achieving the highest potential score for the improvement activities performance category, as well as with our priorities for transforming clinical practice (81 FR 77191). Activities that require performance of multiple actions, such as participation in the Transforming Clinical Practice Initiative (TCPI), participation in a MIPS eligible clinician’s state Medicaid program, or an activity identified as a public health priority (such as emphasis on anticoagulation management or utilization of prescription drug monitoring programs) were also proposed to be weighted as high (81 FR 77191). We also stated that we believe that high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being (81 FR 77194). In the past, we have given certain improvement activities high weighting due to the intensity of the activity; for example, one improvement activity was changed to high weighting because it often involves travel and work under challenging physical and clinical circumstances (81 FR 77194). Also, we note that successful participation in the CMS Study on Factors Associated with Reporting Quality Measures as discussed in section III.H.3.h.(4)(e) of this proposed rule would result in full credit for the improvement activities performance category of 40 points; if participants do not meet the study guidelines, they will need to follow the current improvement activities guidelines (81 FR 77197).

(bb) Clarifications

In this proposed rule, we are clarifying: (a) Our consideration of giving high-weighting due to activity

intensity; and (b) differences between high- and medium-weighting.

(AA) High-Weighting Due to Activity Intensity

As stated above, we have given certain improvement activities high weighting due to the intensity of the activity (81 FR 77194). To elaborate, we believe that an activity that requires significant investment of time and resources should be high-weighted. For example, we finalized the CAHPS for MIPS survey as high-weighted (81 FR 77827), because it requires a significant investment of time and resources. As part of the requirements of this activity, MIPS eligible clinicians: (1) Must register for the CAHPS for MIPS survey; (2) must select and authorize a CMS-approved survey vendor to collect and report survey data using the survey and specifications provided by us; and (3) are responsible for vendor's costs to collect and report the survey (ranges from approximately \$4,000 to \$7,000 depending on services requested).

In contrast, we believe medium-weighted improvement activities are simpler to complete and require less time and resources as compared to high-weighted improvement activities. For example, we finalized the Cost Display for Laboratory and Radiographic Orders improvement activity as medium-weighted (82 FR 54188), because the information required to be used is readily available (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html>) at no cost through the Medicare clinical laboratory fee schedule and can be distributed in a variety of manners with very little investment (for example, it may be displayed in the clinic, provided to patients through hardcopies, or incorporated in the electronic health record).

(BB) High- Versus Medium-Weighting

We recognize that we did not previously explicitly state separate considerations for medium-weighted activities specifically. This is because an improvement activity is only either high or medium-weighted. In this proposed rule, we are clarifying that an improvement activity is by default medium-weight unless it meets considerations for high-weighting as discussed above.

(cc) Request for Comments

We intend to more thoroughly revisit our improvement activity weighting policies in next year's rulemaking. We invite public comment on the need for

additional transparency and guidance on the weighting of improvement activities as we work to refine the Annual Call for Activities process for future years. Furthermore, in light of the proposed policy to remove bonus points for improvement activities that may be applicable to the Promoting Interoperability performance category as discussed in sections III.H.3.h.(4)(d)(i)(A)(cc) and III.H.3.h.(5)(d)(ii), we recognize the need to continue incentives for CEHRT. Therefore, for future consideration, we are seeking comment on potentially applying high-weighting for any improvement activity employing CEHRT. We also invite public comment on any other additional considerations for high- or medium-weighting.

(D) Timeframe for the Annual Call for Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would accept submissions for prospective improvement activities and modifications to existing improvement activities at any time during the performance period to be added to the Improvement Activities Under Review (IAUR) list, for the applicable performance period, which would be displayed on a CMS website following the close of the Call for Activities. In addition, we finalized that for the Annual Call for Activities, only nominations and modifications submitted by March 1st would be considered for inclusion in the IAUR list and Improvement Activities Inventory for the performance period occurring in the following calendar year (82 FR 53660). For example, for the CY 2018 Call for Activities, we received nominations for new and modified improvement activities from February 1st through March 1st. Currently, an improvement activity nomination submitted during the CY 2018 Annual Call for Activities would be vetted in CY 2018, and after review, if accepted by CMS, would be proposed during the CY 2018 rulemaking cycle for possible implementation in the CY 2019 performance period and future years.

However, the previously established timeline, which includes prospective new and modified improvement activities submission period, review, and publication of proposed improvement activities for implementation in the next performance period, has become operationally challenging. Based on our experience over the past 2 years, we have found that processing and reviewing the

volume of improvement activities nominations requires more time than originally thought. In addition, preparations and drafting for annual rulemaking begin around the time of the close date for the current Call for Activities (that is, March 1st), leaving incorporation into the proposed rule challenging. Therefore, in this proposed rule, beginning with the CY 2019 performance period and future years, we are proposing to: (1) Delay the year for which nominations of prospective new and modified improvement activities would apply; and (2) expand the submission timeframe/due date for nominations.

Beginning with the CY 2019 performance period and for future years, we are proposing to change the performance year for which the nominations of prospective new and modified improvement activities would apply, such that improvement activities nominations received in a particular year will be vetted and considered for the next year's rulemaking cycle for possible implementation in a future year. This timeframe parallels the Promoting Interoperability performance category Annual Call for EHR Measures timeframe found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/CallForMeasures.html>. For example, an improvement activity nomination submitted during the CY 2020 Annual Call for Activities would be vetted, and if accepted by CMS, would be proposed during the CY 2021 rulemaking cycle for possible implementation starting in CY 2022. We believe this change will give us adequate time to thoroughly vet improvement activity nominations prior to rulemaking.

Second, beginning with the CY 2019 performance period, we are proposing to change the submission timeframe for the Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately 4 additional months for stakeholders to submit nominations. We believe this change will assist stakeholders by providing additional time to submit improvement activities nominations. Consistent with previous policy, nominations for prospective new and modified improvement activities would be accepted during the Call for Activities time period only and would be included in the IAUR displayed on a CMS website following the close of the Annual Call for Activities.

(ii) Proposed New Improvement Activities and Modifications to and Removal of Existing Improvement Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would add new improvement activities to the Improvement Activities Inventory through notice-and-comment rulemaking. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) and Table F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229) for our previously finalized Improvement Activities Inventory. In this proposed rule, for CY 2019 performance period and future years, we are proposing 6 new improvement activities; we are also proposing to: (1) Modify 5 existing activities; and (2) remove 1 existing activity. We refer readers to the Improvement Activities Inventory in Tables A and B of Appendix 2 of this proposed rule for further details. We are also proposing changes to our CMS Study on Factors Associated with Reporting Quality Measures in section III.H.3.h.(4)(e) of this proposed rule.

We invite public comments on the proposed new activities and modifications to and removal of existing activities listed in the Improvement Activities Inventory for the CY 2019 performance period and future years.

(e) CMS Study on Factors Associated With Reporting Quality Measures

(i) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77195), we created the Study on Improvement Activities and Measurement. In CMS' quest to create a culture of improvement using evidence based medicine on a consistent basis, fully understanding the strengths and limitations of the current processes is crucial to better understand the current processes. We proposed to conduct a study on clinical improvement activities and measurement to examine clinical quality workflows and data capture using a simpler approach to quality measures (81 FR 77196). The lessons learned in this study on practice improvement and measurement may influence changes to future MIPS data submission requirements. The goals of the study are to see whether there will be improved outcomes, reduced burden in reporting, and enhancements in clinical care by selected MIPS eligible clinicians (81 FR 77196). This study shall inform us on the root causes of

clinicians' performance measure data collection and submission burdens, as well as challenges that hinder accurate and timely quality measurement activities. Our goals are to use high quality, low cost measures that are meaningful, easy to understand, operable, reliable, and valid. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77195) the CMS Study on Burden Associated with Quality Reporting goals are to see whether there will be improved outcomes, reduced burden in reporting, and enhancements in clinical care by selected MIPS eligible clinicians desiring:

- A more data driven approach to quality measurement.
- Measure selection unconstrained by a CEHRT program or system.
- Improving data quality submitted to CMS.
- Enabling CMS to get data more frequently and provide feedback more often.

This study evolved into "CMS Study on Burdens Associated with Reporting Quality Measures" in the CY 2018 Quality Payment Program final rule (82 FR 53662).

This study is ongoing, participants are recruited on a yearly basis for a minimum period of 3 years, and current participants can opt-in or out when the study year ends (81 FR 77195). Successful participation in the study would result in full credit for the improvement activities performance category of 40 points; if participants do not meet the study guidelines, they will need to follow the current improvement activities requirements (81 FR 77197). To meet the study requirements, study participants must partake in two web-based survey questionnaires, submit data for at least three MIPS clinician quality measures to CMS during the CY 2019 performance period, and be available for selection and participation in at least one focus group meeting (82 FR 53662).

While we are not proposing any changes to the study purpose, aim, eligibility, or credit, we are proposing, for the CY 2019 performance period and future years, changes to the: (1) Title of the study; (2) sample size to allow enough statistical power for rigorous analysis within some categories, (3) focus group and survey requirements; and (4) measure requirements. These proposals are discussed in more detail below.

(ii) Title

Beginning with the CY 2019 performance period, we are proposing to change the title of the study from "CMS

Study on Burdens Associated with Reporting Quality Measures" to "CMS Study on Factors Associated with Reporting Quality Measures" to more accurately reflect the study's intent and purpose. To assess the root causes of clinician burden associated with the collection and submission of clinician quality measures for MIPS, as depicted in CY 2017 Quality Payment Program final rule (81 FR 77195), replacing "Burden" with "Factors" in the title will eliminate possible response or recall bias that may occur with data collection. Having "burden" in the study title may elicit the tendency of survey participants reporting more on their perception of burden and challenges, and/or suppressing other factors that are associated with their quality measure data collection and submission, that may be relevant to examining the root cause of burden.

(iii) Sample Size

(A) Current Policy

In the CY 2017 Quality Payment Program final rule (81 FR 77196), we initially finalized a sample size of 42 participants (comprising of groups and individual MIPS eligible facilities). In the CY 2018 Quality Payment Program final rule (82 FR 53661), we increased that number and finalized a sample size of a minimum of 102 individual and group participants for performance periods occurring in CY 2018 for the following categories:

- 20 urban individuals or groups of <3 eligible clinicians—(broken down into 10 individuals & 10 groups).
- 20 rural individuals or groups of <3 eligible clinicians—(broken down into 10 individuals & 10 groups).
- 10 groups of 3–8 eligible clinicians.
- 10 groups of 8–20 eligible clinicians.
- 10 groups of 20–100 eligible clinicians.
- 10 groups of 100 or greater eligible clinicians.
- 6 groups of >20 eligible clinicians reporting as individuals—(broken down into 3 urban & 3 rural).
- 6 specialty groups—(broken down into 3 reporting individually & 3 reporting as a group).
- Up to 10 non-MIPS eligible clinicians reporting as a group or individual (any number of individuals and any group size).

(B) Proposed New Sample Size

In this proposed rule, we are proposing to again increase the sample size for the CY 2019 performance period and future years from a minimum of 102 to a minimum of 200 MIPS eligible

clinicians, which will enable us to more rigorously analyze the statistical difference between the burden and factors associated within the categories listed above. This proposed increase in sample size would provide the minimum sample needed to get a significant result with adequate statistical power to determine whether there are any statistically significant differences in quality measurement data submission associated with: (1) The size of practice or facility; (2) clinician specialty of practice; (3) region of practice; (4) individual or group reporting; and (5) clinician quality measure type. This rigorous statistical analysis is important, because it facilitates tracing the root causes of measurement burdens and data submission errors that may be associated with various sub-groups of clinician practices using quantitative analytical methods. We believe that a larger sample size would also account for any attrition (drop out of study participants before the study ends). Therefore, we are proposing that the new sample size distribution would be:

- 40 urban individuals or groups of <3 eligible clinicians—(broken down into 20 individuals & 20 groups).
- 40 rural individuals or groups of <3 eligible clinicians—(broken down into 20 individuals & 20 groups).
- 20 groups of 3–8 eligible clinicians.
- 20 groups of 8–20 eligible clinicians.
- 20 groups of 20–100 eligible clinicians.
- 20 groups of 100 or greater eligible clinicians.
- Up to 6 groups of >20 eligible clinicians reporting as individuals—(broken down into 3 urban & 3 rural).
- Up to 6 specialty groups—(broken down into 3 reporting individually & 3 reporting as a group).
- Up to 10 non-MIPS eligible clinicians reporting as a group or individual (any number of individuals and any group size).

(iv) Focus Group

(A) Current Policies

We previously finalized in the CY 2017 Quality Payment Program final rule (81 FR 77195) that for the transition year of MIPS, study participants were required to attend a monthly focus group to share lessons learned in submitting quality data along with providing survey feedback to monitor effectiveness. The focus group includes providing visual displays of data, workflows, and best practices to share amongst the participants to obtain feedback and make further

improvements (81 FR 77196). The focus groups are used to learn from the practices about how to be more agile as we test new ways of measure recording and workflow (81 FR 77196). In the CY 2018 Quality Payment Program final rule (82 FR 53662), for Year 2 and future years, we reduced that requirement and finalized that study participants would be required to complete at least two web-based survey questionnaire and attend up to 4 focus group sessions throughout the year, but certain study participants would be able to attend less frequently. Each study participant is required to complete a survey prior to submitting MIPS data and another survey after submitting MIPS data (82 FR 53662). The purpose of reducing focus group attendance and survey participation was to ease requirements for MIPS eligible clinicians or group of clinicians who may have nothing new to contribute, without compromising the minimum sample needed for focus groups. For example, if a MIPS eligible clinician submitted all 6 measures after collecting 90 days of data and attended the first available focus group and/or survey, the clinician may have nothing new or relevant to discuss with the research team on subsequent focus groups and/or surveys.

(B) Proposed New Requirements for Focus Group and Survey Participation

Although we are proposing in the section above to increase the sample size of the study to a minimum of 200 MIPS eligible clinicians, we do not believe we need focus groups for the entirety of that population. We believe that requiring focus groups for all proposed minimum of 200 MIPS eligible clinicians would only result in bringing the data to a saturation point, a situation whereby the same themes and information are recurring, and no new insights are given by additional sources of data from focus groups.

Instead, we believe that selecting a subset of clinicians, purposively, to participate in focus groups would be a more appropriate approach because that would allow us to understand the experience of select clinicians without imposing undue burden on all. This study is voluntary as clinicians nominate themselves to participate and we select a cohort from among these volunteers. Therefore, we are proposing to make the focus group participation a requirement only for a selected subset of the study participants, using purposive sampling and random sampling methods, beginning with the CY 2019 performance period and future years. Those who are selected would be required to participate, in at least one

focus group meeting and complete survey requirements, in addition to all the other study requirements. As previously established, each study participant is required to complete a survey prior to submitting MIPS data and another survey after submitting MIPS data. This requirement would continue to apply for each selected subset participating in a focus group.

(v) Measure Requirements

(A) Current Requirements

In the CY 2017 Quality Payment Program final rule (81 FR 77196), we finalized that for CY 2017, the participating MIPS eligible clinicians or groups would submit their data and workflows for a minimum of three MIPS clinician quality measures that are relevant and prioritized by their practice. One of the measures must be an outcome measure, and one must be a patient experience measure (81 FR 77196). We also finalized that for future years, participating MIPS eligible clinicians or groups would select three of the measures for which they have baseline data from the 2017 performance period to compare against later performance years. We note that participating MIPS eligible clinicians could elect to report on more measures originally as this would provide more options from which to select in subsequent years for purposes of measuring improvement. In the CY 2018 Quality Payment Program final rule, we finalized for the Quality Payment Program Year 2 and future years, that study participants could submit all their quality measures data at once, as it is done in the MIPS program, (qpp.cms.gov) (82 FR 53662).

(B) Proposed Measure Requirements

In this proposed rule, we are proposing to continue the previously required minimum number of measures. That is, for the CY 2019 performance period and future years: Participants must submit data and workflows for a minimum of three MIPS quality measures for which they have baseline data. However, instead of requiring one outcome measure and one patient experience measure as previously finalized, we are proposing that, for the CY 2019 performance period and future years, at least one of the minimum of three measures must be a high priority measure as defined at § 414.1305. As defined there and discussed in section III.H.3.h.(2) of this proposed rule, a high priority measure means an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality

measure. Outcome measures includes intermediate-outcome and patient-reported outcome measures. We believe that focusing on high priority measures, rather than patient experience measures, is important at this time, because it better aligns with the MIPS quality measures data submission criteria. We invite public comment on our proposal.

We note that although the aforementioned activities (that is, the CMS Study on Factors Associated with Reporting Quality Measures) constitute an information collection request as defined in the implementing regulations of the Paperwork Reduction Act of 1995 (5 CFR part 1320), the associated burden is exempt from application of the Paperwork Reduction Act. Specifically, section 1848(s) (7) of the Act, as added by section 102 of MACRA (Pub. L. 114–10) states that Chapter 35 of title 44, United States Code, shall not apply to the collection of information for the development of quality measures.

(5) Promoting Interoperability (PI) (Previously Known as the Advancing Care Information Performance Category)

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of CEHRT as a performance category under the MIPS. In prior rulemaking, we referred to this performance category as the advancing care information performance category, and it is reported by MIPS eligible clinicians as part of the overall MIPS program. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the advancing care information performance category.

(b) Renaming the Advancing Care Information Performance Category

In this proposed rule, we are proposing several scoring and measurement policies that would bring the performance category to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information. To better reflect this focus, we renamed the advancing care information performance category to the Promoting Interoperability (PI) performance category. We believe this change will help highlight the enhanced goals of this performance category. We are proposing revisions to the regulation text under 42 CFR part 414, subpart O, to reflect the new name.

(c) Certification Requirements Beginning in 2019

Under the definition of CEHRT under § 414.1305, for the performance periods in 2017 and 2018, MIPS eligible clinicians had flexibility to use EHR technology certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two Editions, to meet the objectives and measures specified for the Promoting Interoperability performance category (82 FR 53671 through 53672). However, beginning with the performance period in 2019, MIPS eligible clinicians must use EHR technology certified to the 2015 Edition certification criteria as specified at § 414.1305. As discussed in this section, we continue to believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019. In reviewing the state of health information technology, it is clear the 2014 Edition certification criterion are out of date and insufficient for clinician needs in the evolving health information technology (IT) industry. It would be beneficial to health IT developers and health care providers to move to more up-to-date standards and functions that better support interoperable exchange of health information and improve clinical workflows.

The 2014 Edition certification criteria, which were first issued in regulations in 2012, now includes standards that are significantly out of date, which can impose limits on interoperability and the access, exchange, and use of health information. Moving from certifying to the 2014 Edition to certifying to the 2015 Edition would also eliminate the inconsistencies that are inherent with maintaining and implementing two separate certification programs. In the last calendar year, the number of new and unique 2014 Edition products have been declining, showing that the market acknowledges the shift towards newer and more effective technologies. The vast majority of 2014 Edition certifications are for inherited certified status. The resulting legacy systems, while certified to the 2014 Edition, are not the most up-to-date and detract from health information technology's goal of increasing interoperability and increasing the access, exchange, and use of health data.

Prolonging backwards compatibility of newer products to legacy systems causes market fragmentation. Health IT stakeholders noted the impact of system fragmentation on the cost to develop and maintain health IT connectivity to support data exchange, develop products to support specialty clinical

care, and integrate software supporting administrative and clinical processes. As previously stated, a large proportion of the sector is ready to use only the 2015 Edition of CEHRT; allowing use of both certification editions contributes to market fragmentation, which heightens implementation costs for health IT developers, clinicians, and other health care providers. Developers and consumers that maintain two different certification editions spend large amounts of money on the recertification of older products, which diverts resources from the development, maintenance, and implementation of more advanced technologies, including 2015 Edition CEHRT.

In addition to the monetary savings resulting from a move to the 2015 Edition, there will also be reduced burden across many settings. MIPS eligible clinicians will see a reduction in burden through the relief from certifying to a legacy system and can use 2015 Edition CEHRT to better streamline workflows and utilize more comprehensive functions to meet patient safety goals and improve care coordination across the continuum. Maintaining only one edition of certification requirements would also reduce the burden for health IT developers, as well as Office of the National Coordinator for Health Information Technology (ONC)-Authorized Testing Laboratories and ONC-Authorized Certification Bodies because they would no longer have to support two, increasingly distant sets of requirements.

One of the major improvements of the 2015 Edition is the Application Programming Interface (API) functionality. The API functionality supports health care providers and patient electronic access to health information. These functions allow for patient data to move between systems and assist patients with making key decisions about their health care. These functions also contribute to quality improvement and greater interoperability between systems. The API has the ability to complement a specific health care provider branded patient portal or could also potentially make one unnecessary if patients are able to use software applications designed to interact with an API that could support their ability to view, download, and transmit their health information to a third party (80 FR 62842). Furthermore, the API allows for third-party application usage with more flexibility and smoother workflow from various systems than what is often found in many current patient portals.

The 2015 Edition also includes certification criterion specifying a core set of data that health care providers have noted are critical to interoperable exchange and can be exchanged across a wide variety of other settings and use cases, known as the Common Clinical Data Set (CCDS) (80 FR 62603). The US Core Data for Interoperability (USCDI) builds off the CCDS definition adopted for the 2015 Edition of certified health IT for instance as the data which must be included in a summary care record. The USCDI aims to support the goals set forth in the 21st Century Cures Act by specifying a common set of data classes that are required for interoperable exchange and identifying a predictable, transparent, and collaborative process for achieving those goals. The USCDI is referenced by the Draft Trusted Exchange Framework (<https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf>), which is intended to enable Healthcare Information Networks (HINs) and Qualified HINs to securely exchange electronic health information in support of a range permitted purposes, including treatment, payment, operations, individual access, public health, and benefits determination.

The 2015 Edition also includes a requirement that products must be able to export data from one patient, a set of patients, or a subset of patients, which is responsive to health care provider feedback that their data is unable to carry over from a previous EHR. The 2014 Edition did not include a requirement that the vendor allow the MIPS eligible clinician to export the data themselves. In the 2015 Edition, the health care provider has the autonomy to export data themselves without intervention by their vendor, resulting in increased interoperability and data exchange in the 2015 Edition.

In efforts to track certification readiness for the 2015 Edition, ONC considers the number of health care providers likely to be served by the

developers seeking certification under the ONC Health IT Certification Program in real time as the testing and certification process progresses. The ONC considers trends within the industry when projecting for 2015 Edition readiness. In working with ONC, we are able to identify the percentage of MIPS eligible clinicians that have a 2015 Edition of CEHRT available to them based on vendor readiness and information. As of the beginning of the first quarter of CY 2018, ONC confirmed that at least 66 percent of MIPS eligible clinicians have 2015 Edition CEHRT available based on previous Medicare and Medicaid EHR Incentive Programs attestation data. Based on these data, and as compared to the transition from 2011 Edition to 2014 Edition, it appears that the transition from the 2014 Edition to the 2015 Edition is on schedule for the performance period in CY 2019.

This information is current as of the beginning of CY 2018, and based on historical data, we expect readiness to continue to improve as developers and health care providers prepare for program participation using the 2015 Edition in CY 2019.

We continue to recognize there is a burden associated with development and deployment of new technology, but we believe requiring use of the most recent version of CEHRT is important in ensuring health care providers will use technology that has improved interoperability features and up-to-date standards to collect and exchange relevant patient health information. The 2015 Edition includes key updates to functions and standards that support improved interoperability and clinical effectiveness through the use of health IT.

(d) Scoring Methodology

(i) Scoring Methodology for 2017 and 2018 Performance Periods

Section 1848(q)(5)(E)(i)(IV) of the Act states that 25 percent of the MIPS final

score shall be based on performance for the Promoting Interoperability performance category. Accordingly, under § 414.1375(a), the Promoting Interoperability performance category comprises 25 percent of a MIPS eligible clinician's final score for the 2019 MIPS payment year and each MIPS payment year thereafter, unless we assign a different scoring weight. We are proposing to revise § 414.1375(a) to specify the various sections of the statute (sections 1848(o)(2)(D), 1848(q)(5)(E)(ii), and 1848(q)(5)(F) of the Act) under which a different scoring weight may be assigned for the Promoting Interoperability performance category. We established the reporting criteria to earn a performance category score for the Promoting Interoperability performance category under § 414.1375(b). We are proposing to revise § 414.1375(b)(2)(i) to replace the reference to "each required measure" with "each base score measure" to improve the precision of the text. Under § 414.1380(b)(4), the Promoting Interoperability performance category score is comprised of a score for participation and reporting, known as the "base score," and a score for performance at varying levels above the base score requirements, known as the "performance score," as well as any applicable bonus scores. We are proposing several editorial changes to § 414.1380(b)(4) in an effort to more clearly and concisely capture the previously established policies. For further explanation of our scoring policies for performance periods in 2017 and 2018 for the Promoting Interoperability performance category, we refer readers to 81 FR 77216 through 77227 and 82 FR 53663 through 53664.

A general summary overview of the scoring methodology for the performance period in 2018 is provided in the Table 35.

TABLE 35—2018 PERFORMANCE PERIOD PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY SCORING METHODOLOGY PROMOTING INTEROPERABILITY OBJECTIVES AND MEASURES

2018 Promoting interoperability objective	2018 Promoting interoperability measure	Required/not required for base score (50%)	Performance score (up to 90%)	Reporting requirement
Protect Patient Health Information ..	Security Risk Analysis	Required	0	Yes/No Statement.
Electronic Prescribing	e-Prescribing **	Required	0	Numerator/Denominator.
Patient Electronic Access	Provide Patient Access	Required	Up to 10	Numerator/Denominator.
	Patient-Specific Education	Not Required	Up to 10	Numerator/Denominator.
Coordination of Care Through Patient Engagement.	View, Download, or Transmit (VDT)	Not Required	Up to 10	Numerator/Denominator.
	Secure Messaging	Not Required	Up to 10	Numerator/Denominator.
	Patient-Generated Health Data	Not Required	Up to 10	Numerator/Denominator.
Health Information Exchange	Send a Summary of Care **	Required	Up to 10	Numerator/Denominator.

TABLE 35—2018 PERFORMANCE PERIOD PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY SCORING METHODOLOGY PROMOTING INTEROPERABILITY OBJECTIVES AND MEASURES—Continued

2018 Promoting interoperability objective	2018 Promoting interoperability measure	Required/not required for base score (50%)	Performance score (up to 90%)	Reporting requirement
Public Health and Clinical Data Registry Reporting.	Request/Accept Care **.	Required	Up to 10	Numerator/Denominator.
	Clinical Information Reconciliation ..	Not Required	Up to 10	Numerator/Denominator.
	Immunization Registry Reporting	Not Required	0 or 10 *	Yes/No Statement.
	Syndromic Surveillance Reporting ..	Not Required	0 or 10 *	Yes/No Statement.
	Electronic Case Reporting	Not Required	0 or 10 *	Yes/No Statement.
	Public Health Registry Reporting	Not Required	0 or 10 *	Yes/No Statement.
	Clinical Data Registry Reporting	Not Required	0 or 10 *	Yes/No Statement.
Bonus (up to 25%)				
Report to one or more additional public health agencies or clinical data registries beyond the one identified for the performance score.		5% bonus		Yes/No Statement.
Report improvement activities using CEHRT		10% bonus		Yes/No Statement.
Report using only 2015 Edition CEHRT		10% bonus		Based on measures submitted.

* A MIPS eligible clinician may earn 10 percent for each public health agency or clinical data registry to which the clinician reports, up to a maximum of 10 percent under the performance score.

** Exclusions are available for these measures.

We heard from many stakeholders that the current scoring methodology is complicated and difficult to understand. In fact, we have received hundreds of questions requesting clarification of various aspects of the scoring methodology. For example, many clinicians asked how many performance score measures they should submit. By providing flexibility and offering clinicians multiple measures to choose from within the performance score, it appears some clinicians may have been confused by the options. Other MIPS eligible clinicians have indicated that they dislike the base score because it is a required set of measures and provides no flexibility because the scoring is all or nothing. If a MIPS eligible clinician cannot fulfill the base score, they cannot earn a performance and/or bonus score. We have also received feedback from clinicians and specialty societies that the current requirements detract from their ability to provide care to their patients. In addition, stakeholders have indicated that the requirements of the Promoting Interoperability performance category for clinicians do not align with the requirements of the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs) and that this creates a burden for the medical staff who are tasked with overseeing the participation of both clinicians and hospitals in these programs.

Based on the concerns expressed by stakeholders, we are proposing a new scoring methodology and moving away

from the base, performance and bonus score methodology that we currently use. We believe this change would provide a simpler, more flexible, less burdensome structure, allowing MIPS eligible clinicians to put their focus back on patients. The introduction of this new scoring methodology would continue to encourage MIPS eligible clinicians to push themselves on measures that are most applicable to how they deliver care to patients, instead of focusing on measures that may not be as applicable to them. Our goal is to provide increased flexibility to MIPS eligible clinicians and enable them to focus more on patient care and health data exchange through interoperability. Additionally, we want to align the requirements of the Promoting Interoperability performance category with the requirements of the Medicare Promoting Interoperability Program for eligible hospitals and CAHs as we have proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20518 through 20537). As the distinction between ambulatory and inpatient CEHRT has diminished and more clinicians are sharing hospitals' CEHRT, we believe that aligning the requirements between programs would lessen the burden on health care providers and facilitate their participation in both programs.

(ii) Proposed Scoring Methodology Beginning With the MIPS Performance Period in 2019

We are proposing a new scoring methodology, beginning with the performance period in 2019, to include a combination of new measures, as well as the existing Promoting Interoperability performance category measures, broken into a smaller set of four objectives and scored based on performance. We believe this is an overhaul of the existing program requirements as it eliminates the concept of base and performance scores. The smaller set of objectives would include e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. We are proposing these objectives to promote specific HHS priorities and satisfy the requirements of section 1848(o)(2) of the Act. We include the e-Prescribing and Health Information Exchange objectives in part to capture what we believe are core goals for the 2015 Edition of CEHRT and also to satisfy the statutory requirements. These core goals promote interoperability between health care providers and health IT systems to support safer, more coordinated care. The Provider to Patient Exchange objective promotes patient awareness and involvement in their health care through the use of APIs, and ensures patients have access to their medical data. Finally, the Public Health and Clinical Data Exchange objective supports the ongoing systematic

collection, analysis, and interpretation of data that may be used in the prevention and controlling of disease through the estimation of health status and behavior. The integration of health IT systems into the national network of health data tracking and promotion improves the efficiency, timeliness, and effectiveness of public health surveillance. We believe it is important to keep these core goals, primarily because these objectives promote interoperability between health care providers and health IT systems to support safer, more coordinated care while ensuring patients have access to their medical data.

Under the proposed scoring methodology, MIPS eligible clinicians would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level. Each measure would be scored based on the MIPS eligible clinician's performance for that measure, based on the submission of a numerator and denominator, except for the measures associated with the Public Health and Clinical Data Exchange objective, which require "yes or no" submissions. Each measure would contribute to the MIPS eligible clinician's total Promoting Interoperability performance category score. The scores for each of the individual measures would be added together to calculate the Promoting Interoperability performance category score of up to 100 possible points for each MIPS eligible clinician. In general, the Promoting Interoperability performance category score makes up 25 percent of the MIPS final score. If a MIPS eligible clinician fails to report on a required measure or claim an exclusion for a required measure if applicable, the clinician would receive a total score of zero for the Promoting Interoperability performance category.

We also considered an alternative approach in which scoring would occur at the objective level, instead of the individual measure level, and MIPS eligible clinicians would be required to report on only one measure from each objective to earn a score for that objective. Under this scoring methodology, instead of six required measures, the MIPS eligible clinician total Promoting Interoperability performance category score would be based on only four measures, one measure from each objective. Each objective would be weighted similarly to how the objectives are weighted in our proposed methodology, and bonus points would be awarded for reporting any additional measures beyond the

required four. We are seeking public comment on this alternative approach, and whether additional flexibilities should be considered, such as allowing MIPS eligible clinicians to select which measures to report on within an objective and how those objectives should be weighted, as well as whether additional scoring approaches or methodologies should be considered.

In our proposed scoring methodology, the e-Prescribing objective would contain three measures each weighted differently to reflect their potential availability and applicability to the clinician community. In addition to the existing e-Prescribing measure, we are proposing to add two new measures to the e-Prescribing objective: Query of Prescription Drug Monitoring Program (PDMP); and Verify Opioid Treatment Agreement. For more information about these two proposed measures, we refer readers to section III.H.3.h.(5)(f) of this proposed rule. The e-Prescribing measure would be required for reporting and weighted at 10 points because we believe it would be applicable to most MIPS eligible clinicians. In the event that a MIPS eligible clinician meets the criteria and claims the exclusion for the e-Prescribing measure in 2019, the 10 points available for that measure would be redistributed equally among the two measures under the Health Information Exchange objective:

- Support Electronic Referral Loops By Sending Health Information Measure (25 points)
- Support Electronic Referral Loops By Receiving and Incorporating Health Information (25 points)

We are seeking public comment on whether this redistribution is appropriate for 2019, or whether the points should be distributed differently.

The Query of PDMP and Verify Opioid Treatment Agreement measures would be optional for the MIPS performance period in 2019. These new measures may not be available to all MIPS eligible clinicians for the MIPS performance period in 2019 as they may not have been fully developed by their health IT vendor, or not fully implemented in time for data capture and reporting. Therefore, we are not proposing to require these two new measures in 2019, although MIPS eligible clinicians may choose to report them and earn up to 5 bonus points for each measure. We are proposing to require these measures beginning with the MIPS performance period in 2020, and we are seeking public comment on this proposal. Due to varying State requirements, not all MIPS eligible clinicians would be able to e-prescribe controlled substances, and thus, these

measures would not be available to them. For these reasons, we are proposing an exclusion for these two measures beginning with the MIPS performance period in 2020. The exclusion would provide that any MIPS eligible clinician who is unable to report the measure in accordance with applicable law would be excluded from reporting the measure, and the 5 points assigned to that measure would be redistributed to the e-Prescribing measure.

As the two new opioid measures become more broadly available in CEHRT, we are proposing each of the three measures within the e-Prescribing objective would be worth 5 points beginning with the MIPS performance period in 2020. Requiring these two measures would add 10 points to the maximum total score for the Promoting Interoperability performance category as these measures would no longer be eligible for optional bonus points. To maintain a maximum total score of 100 points, beginning with the MIPS performance period in 2020, we are proposing to reweight the e-Prescribing measure from 10 points down to 5 points, and reweight the Provide Patients Electronic Access to Their Health Information measure from 40 points down to 35 points as illustrated in Table 36. We are proposing that if the MIPS eligible clinician qualifies for the e-Prescribing exclusion and is excluded from reporting all three of the measures associated with the e-Prescribing objective as described in section III.H.3.h.(5)(f) of this proposed rule, the 15 points for the e-Prescribing objective would be redistributed evenly among the two measures associated with the Health Information Exchange objective and the Provide Patients Electronic Access to their Health Information measure by adding 5 points to each measure.

For the Health Information Exchange objective, we are proposing to change the name of the existing Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information, and proposing a new measure which combines the functionality of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures into a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information. For more information about the proposed measure and measure changes, we refer readers to section III.H.3.h.(5)(f) of this proposed rule. MIPS eligible clinicians would be required to report both of these measures, each worth 20 points toward their total Promoting

Interoperability performance category score. These measures are weighted heavily to emphasize the importance of sharing health information through interoperable exchange in an effort to promote care coordination and better patient outcomes. Similar to the two new measures in the e-Prescribing objective, the new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure may not be available to all MIPS eligible clinicians as it may not have been fully developed by their health IT vendor, or not fully implemented in time for a MIPS performance period in 2019. For these reasons, we are proposing an exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure: Any MIPS eligible clinician who is unable to implement the measure for a MIPS performance period in 2019 would be excluded from having to report this measure.

In the event that a MIPS eligible clinician claims an exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, the 20 points would be redistributed to the Support Electronic Referral Loops by Sending Health Information measure, and that measure would then be worth 40 points. We are seeking public comment on whether this redistribution is appropriate, or whether the points should be redistributed to other measures instead.

We are proposing to weight the one measure in the Provider to Patient Exchange objective, Provide Patients Electronic Access to Their Health Information, at 40 points toward the total Promoting Interoperability performance category score in 2019 and 35 points beginning in 2020. We are proposing that this measure would be weighted at 35 points beginning in 2020 to account for the two new opioid measures, which would be worth 5 points each beginning in 2020 as proposed above. We believe this objective and its associated measure get to the core of improved access and exchange of patient data in Promoting Interoperability and are the crux of the Promoting Interoperability performance category. This exchange of data between health care provider and patient is imperative in order to continue to improve interoperability, data exchange and improved health outcomes. We believe that it is important for patients to have control over their own health information, and through this highly weighted objective we are aiming to show our dedication to this effort.

The measures under the Public Health and Clinical Data Exchange objective are reported using “yes or no” responses and thus we are proposing to score those measures on a pass/fail basis in which the MIPS eligible clinician would receive the full 10 points for reporting two “yes” responses, or for submitting a “yes” for one measure and claiming an exclusion for another. If there are no “yes” responses and two exclusions are claimed, the 10 points would be redistributed to the Provide Patients Electronic Access to Their Health Information measure. A MIPS eligible clinician would receive zero points for reporting “no” responses for the measures in this objective if they do not submit a “yes” or claim an exclusion for at least two measures under this objective. We are proposing that for this objective, the MIPS eligible clinician would be required to report on two measures of their choice from the following list of measures: Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting. To account for the possibility that not all of the measures under the Public Health and Clinical Data Exchange objective may be applicable to all MIPS eligible clinicians, we are proposing to establish exclusions for these measures as described in section III.H.3.h.(5)(f) of this proposed rule. If a MIPS eligible clinician claims two exclusions, the 10 points for this objective would be redistributed to the Provide Patients Electronic Access to their Health Information measure under the Provider to Patient Exchange objective, making that measure worth 50 points in 2019 and 45 points beginning in 2020. Reporting more than two measures for this objective would not earn the MIPS eligible clinician any additional points. We refer readers to section III.H.3.h.(5)(f) of this proposed rule in regard to the proposals for the Public Health and Clinical Data Exchange objective and its associated measures.

We propose that the Protect Patient Health Information objective and its associated measure, Security Risk Analysis, would remain part of the requirements for the Promoting Interoperability performance category, but would no longer be scored as a measure and would not contribute to the MIPS eligible clinician’s Promoting Interoperability performance category score. To earn any score in the Promoting Interoperability performance category, we are proposing a MIPS eligible clinician would have to report

that they completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the performance period occurs. We believe the Security Risk Analysis measure involves critical tasks and note that the HIPAA Security Rule requires covered entities to conduct a risk assessment of their healthcare organization. This risk assessment will help MIPS eligible clinicians comply with HIPAA’s administrative, physical, and technical safeguards. Therefore, we believe that every MIPS eligible clinician should already be meeting the requirements for this objective and measure as it is a requirement of HIPAA. We still believe this objective and its associated measure are imperative in ensuring the safe delivery of patient health data. As a result, we would maintain the Security Risk Analysis measure as part of the Promoting Interoperability performance category, but we would not score the measure.

Similar to how MIPS eligible clinicians currently submit data, the MIPS eligible clinician would submit their numerator and denominator data for each measure, and a “yes or no” response for each of the two reported measures under the Public Health and Clinical Data Exchange objective. The numerator and denominator for each measure would then translate to a performance rate for that measure and would be applied to the total possible points for that measure. For example, the e-Prescribing measure is worth 10 points. A numerator of 200 and denominator of 250 would yield a performance rate of $(200/250) = 80$ percent. This 80 percent would be applied to the 10 total points available for the e-Prescribing measure to determine the measure score. A performance rate of 80 percent for the e-Prescribing measure would equate to a measure score of 8 points (performance rate * total possible measure points = points awarded toward the total Promoting Interoperability performance category score; $80 \text{ percent} * 10 = 8$ points). To calculate the Promoting Interoperability performance category score, the measure scores would be added together, and the total sum would be divided by the total possible points (100). The total sum cannot exceed the total possible points. This calculation results in a fraction from zero to 1, which can be formatted as a percent. For example, using the numerical values in Table 38, a total score of 83 points would be converted to a performance category score of 83 percent (total score/total possible score for the Promoting

Interoperability performance category = 83 points/100 points). The Promoting Interoperability performance category score would be multiplied by the performance category weight (which is ultimately multiplied by 100) to get 20.75 points toward the final score ((83 percent * 25 percent * 100) = 20.75 points toward the final score.) These calculations and application to the total Promoting Interoperability performance category score, as well as an example of how they would apply, are set out in Tables 36, 37, and 38.

When calculating the performance rates, measure and objective scores, and Promoting Interoperability performance category score, we would generally round to the nearest whole number. For

example if a MIPS eligible clinician received a score of 8.53 the nearest whole number would be 9. Similarly, if the MIPS eligible clinician received a score of 8.33 the nearest whole number would be 8. In the event that the MIPS eligible clinician receives a performance rate or measure score of less than 0.5, as long as the MIPS eligible clinician reported on at least one patient for a given measure, a score of 1 would be awarded for that measure. We believe this is the best method for the issues that might arise with the decimal points and is the easiest for computations.

In order to meet statutory requirements and HHS priorities, the MIPS eligible clinician would need to report on all of the required measures

across all objectives in order to earn any score at all for the Promoting Interoperability performance category. Failure to report any required measure, or reporting a “no” response on a “yes or no” response measure, unless an exclusion applies would result in a score of zero. We are seeking public comment on the proposed requirement to report on all required measures, or whether reporting on a smaller subset of optional measures would be appropriate.

Tables 36, 37, and 38 illustrate our proposal for the new scoring methodology and an example of application of the proposed scoring methodology.

TABLE 36—PROPOSED SCORING METHODOLOGY FOR THE MIPS PERFORMANCE PERIOD IN 2019

Objectives	Measures	Maximum points
e-Prescribing	e-Prescribing	10 points.
	<i>Bonus:</i> Query of Prescription Drug Monitoring Program (PDMP)	5 points bonus.
	<i>Bonus:</i> Verify Opioid Treatment Agreement	5 points bonus.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	20 points.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points.
Public Health and Clinical Data Exchange	<i>Choose two of the following:</i>	10 points.
	Immunization Registry Reporting.	
	Electronic Case Reporting.	
	Public Health Registry Reporting.	
	Clinical Data Registry Reporting.	
	Syndromic Surveillance Reporting.	

TABLE 37—PROPOSED SCORING METHODOLOGY BEGINNING WITH MIPS PERFORMANCE PERIOD IN 2020

Objectives	Measures	Maximum points
e-Prescribing	e-Prescribing	5 points.
	Query of Prescription Drug Monitoring Program (PDMP)	5 points.
	Verify Opioid Treatment Agreement	5 points.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	20 points.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	35 points.
Public Health and Clinical Data Exchange	<i>Choose two of the following:</i>	10 points.
	Immunization Registry Reporting.	
	Electronic Case Reporting.	
	Public Health Registry Reporting.	
	Clinical Data Registry Reporting.	
	Syndromic Surveillance Reporting.	

We are seeking public comment on whether these measures are weighted appropriately, or whether a different weighting distribution, such as equal

distribution across all measures would be better suited to this program and this proposed scoring methodology. We are also seeking public comment on other

scoring methodologies such as the alternative we considered and outlined earlier in this section.

TABLE 38—PROPOSED SCORING METHODOLOGY FOR THE MIPS PERFORMANCE PERIOD IN 2019 EXAMPLE

Objective	Measures	Maximum points	Numerator/denominator	Performance rate (%)	Score
e-Prescribing	e-Prescribing	10	200/250	80	10 * 0.8 = 8 points.
	Query of Prescription Drug Monitoring Program	5	150/175	86	5 bonus points.
	Verify Opioid Treatment Agreement	5	N/A	N/A	0 points.

TABLE 38—PROPOSED SCORING METHODOLOGY FOR THE MIPS PERFORMANCE PERIOD IN 2019 EXAMPLE—Continued

Objective	Measures	Maximum points	Numerator/denominator	Performance rate (%)	Score
Health Information Exchange.	Support Electronic Referral Loops by Sending Health Information.	20	135/185	73	20 * 0.73 = 15 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	20	145/175	83	20 * 0.83 = 17 points.
Provider to Patient Exchange.	Provide Patients Electronic Access to Their Health Information.	40	350/500	70	40 * 0.70 = 28 points.
Public Health and Clinical Data Exchange.	Immunization Registry Reporting	10	Yes	N/A	10 points.
	Public Health Registry Reporting	Yes	N/A	10 points.
Total Score	83 points.

If we do not finalize a new scoring methodology, we propose to maintain for the performance period in 2019 the current Promoting Interoperability performance category scoring methodology with the same objectives, measures and requirements as established for the performance period in 2018, except that we would discontinue the 2018 Promoting Interoperability Transition Objectives and Measures (82 FR 53677). We would discontinue the use of the transition measures because they are associated with 2014 Edition CEHRT and we are requiring the use of 2015 Edition CEHRT solely beginning with the performance period in 2019. For more information, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53663 through 53680). In addition, we propose to include the 2 new opioid measures, if finalized. We refer readers to section III.H.3.h.(5)(f) of this proposed rule for a discussion of the measure proposals.

We also are seeking public comment on the feasibility of the proposed new scoring methodology in 2019 and whether MIPS eligible clinicians would be able to implement the new measures and reporting requirements under this scoring methodology. In addition, in section III.H.3.h.(5) of this proposed rule, we are seeking public comment on how the Promoting Interoperability performance category should evolve in future years regarding the new scoring methodology and related aspects of the program.

We are proposing to codify the proposed new scoring methodology in new paragraphs (b)(4)(ii) and (iii) under § 414.1380.

(e) Promoting Interoperability/ Advancing Care Information Objectives and Measures Specifications for the 2018 Performance Period

The Advancing Care Information (now Promoting Interoperability)

performance category Objectives and Measures for the 2018 performance period are as follows. For more information, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77227 through 77229, and 82 FR 53674 through 53680, respectively).

Objective: Protect Patient Health Information.

Objective: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

Security Risk Analysis Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by CEHRT in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.

Objective: Electronic Prescribing.

Objective: Generate and transmit permissible prescriptions electronically.

e-Prescribing Measure: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.

Denominator: Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.

Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

Exclusion: Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.

Objective: Patient Electronic Access.

Objective: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

Patient Access Measure: For at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.

Denominator: The number of unique patients seen by the MIPS eligible clinician during the performance period.

Numerator: The number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.

Patient-Specific Education Measure: The MIPS eligible clinician must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to at least one unique patient seen by the MIPS eligible clinician.

Denominator: The number of unique patients seen by the MIPS eligible

clinician during the performance period.

Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT during the performance period.

Objective: Coordination of Care Through Patient Engagement.

Objective: Use CEHRT to engage with patients or their authorized representatives about the patient's care.

View, Download, Transmit (VDT)

Measure: During the performance period, at least one unique patient (or patient-authorized representatives) seen by the MIPS eligible clinician actively engages with the EHR made accessible by the MIPS eligible clinician by either: (1) Viewing, downloading or transmitting to a third party their health information; or (2) accessing their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the MIPS eligible clinician's CEHRT; or (3) a combination of (1) and (2).

Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.

Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the performance period and the number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an API during the performance period.

Secure Messaging Measure: For at least one unique patient seen by the MIPS eligible clinician during the performance period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).

Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.

Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative) or in response to a secure message sent by the patient (or patient-authorized representative), during the performance period.

Patient-Generated Health Data

Measure: Patient-generated health data or data from a non-clinical setting is

incorporated into the CEHRT for at least one unique patient seen by the MIPS eligible clinician during the performance period.

Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.

Numerator: The number of patients in the denominator for whom data from non-clinical settings, which may include patient-generated health data, is captured through the CEHRT into the patient record during the performance period.

Objective: Health Information Exchange.

Objective: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of CEHRT.

Send a Summary of Care Measure: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

Denominator: Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician.

Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.

Exclusion: Any MIPS eligible clinician who transfers a patient to another setting or refers a patient is fewer than 100 times during the performance period.

Request/Accept Summary of Care Measure: For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician receives or retrieves and incorporates into the patient's record an electronic summary of care document.

Denominator: Number of patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition or referral or has never before encountered the patient and for which

an electronic summary of care record is available.

Numerator: Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the clinician into the CEHRT.

Exclusion: Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.

Clinical Information Reconciliation

Measure: For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician performs clinical information reconciliation. The MIPS eligible clinician must implement clinical information reconciliation for the following three clinical information sets: (1) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy. Review of the patient's known medication allergies; and (3) Current Problem list. Review of the patient's current and active diagnoses.

Denominator: Number of transitions of care or referrals during the performance period for which the MIPS eligible clinician was the recipient of the transition or referral or has never before encountered the patient.

Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list; medication allergy list; and current problem list.

Objective: Public Health and Clinical Data Registry Reporting.

Objective: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

Immunization Registry Reporting

Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

Syndromic Surveillance Reporting

Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.

Electronic Case Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.

Public Health Registry Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.

Clinical Data Registry Reporting Measure: The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.

(f) Promoting Interoperability Performance Category Measure Proposals for MIPS Eligible Clinicians

(i) Measure Proposal Summary Overview

We are proposing to adopt beginning with the performance period in 2019 the existing Promoting Interoperability objectives and measures as finalized in the CY 2018 Quality Payment Program final rule (82 FR 53674 through 53680) with several proposed changes as discussed herein, including the addition of new measures, removal of some of the existing measures, and modifications to the specifications of some of the existing measures. We are not proposing to continue the Promoting Interoperability transition objectives and measures (see 82 FR 53674 through 53676) beyond the 2018 MIPS performance period because the 2015 Edition of CEHRT will be required beginning with the MIPS performance period in 2019. Our intent for these proposed changes is to ensure the measures better focus on the effective use of health IT, particularly for interoperability, and to address concerns stakeholders have raised through public forums and in public comments related to the perceived burden associated with the current measures in the program. As stated in the CY 2017 Quality Payment Program final rule (81 FR 77216) our priority is to finalize reporting requirements for the Promoting Interoperability performance category that incentivizes performance and reporting with minimal complexity and reporting burden. In addition, we acknowledged that while we believe all of the measures of the Promoting Interoperability performance category are important, we must also balance the need for these data with data collection and reporting burden (81 FR 77221).

In CY 2017, we initiated an informal process outside of rulemaking for submission of new Promoting Interoperability performance category measures for potential inclusion in the Year 3 Quality Payment Program

proposed rule. We prioritized measures that build on interoperability and health information exchange, the advanced use of CEHRT using 2015 Edition Standards and Certification Criteria, improve program efficiency and flexibility, measure patient outcomes, emphasize patient safety, and support improvement activities and quality performance categories of MIPS. In addition, and as we indicated in the CY 2018 Quality Payment Program proposed rule (82 FR 30079), we sought new measures that may be more broadly applicable to MIPS eligible clinicians who are Nurse Practitioners (NPs), Physician Assistants (PAs), Certified Registered Nurse Anesthetists (CRNAs) and Clinical Nurse Specialists (CNSs).

During this initial submission period, various MIPS eligible clinicians, stakeholders and health IT developers submitted new measures for consideration via an application posted on the CMS website, now hosted at <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/CallForMeasures.html>. Through our review process, which included representation from the ONC, as well as various stakeholder listening sessions, we identified measure submissions that met our criteria and aligned with the Promoting Interoperability performance category goals and priorities, as well as broader HHS initiatives related to the opioid crisis.¹⁸ As a result of this process, we are proposing two measures, Query of PDMP and Verify Opioid Treatment Agreement.

We are proposing to remove six measures from the Promoting Interoperability objectives and measures beginning with the performance period in 2019. Two of the measures we are proposing to remove—Request/Accept Summary of Care and Clinical Information Reconciliation—would be replaced by the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, which combines the functionalities and goals of the two measures it is replacing. Four of the measures—Patient-Specific Education; Secure Messaging; View, Download, or Transmit; and Patient-Generated Health Data—would be removed because they have proven burdensome to MIPS eligible clinicians in ways that were unintended and may detract from clinicians' progress on current program priorities. While the measures proposed for removal would no longer need to be

submitted if we finalize the proposal to remove them, MIPS eligible clinicians may still continue to use the standards and functions of those measures based on the preferences of their patients and their practice needs. We believe that this burden reduction would enable MIPS eligible clinicians to focus on new measures that further interoperability, advances of innovation in the use of CEHRT and the exchange of health care information.

As discussed in the proposed scoring methodology in section III.H.3.h.(5)(f) of this proposed rule, we are proposing to add three new measures to the Promoting Interoperability objectives and measures beginning with the performance period in 2019. For the e-Prescribing objective, we are proposing the two new measures referenced above, Query of PDMP and Verify Opioid Treatment Agreement, both of which support HHS initiatives related to the treatment of opioid and substance use disorders by helping health care providers avoid inappropriate prescriptions, improving coordination of prescribing amongst health care providers and focusing on the advanced use of CEHRT. For the Health Information Exchange objective, we are proposing a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information, which builds upon and replaces the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures, while furthering interoperability and the exchange of health information.

We are also proposing to modify some of the existing Promoting Interoperability objectives and measures beginning with the performance period in 2019. We are proposing to rename the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information. In addition, we are proposing to rename the Patient Electronic Access objective to Provider to Patient Exchange, and proposing to rename the remaining measure, Provide Patient Access to Provide Patients Electronic Access to Their Health Information. We are proposing to eliminate the Coordination of Care Through Patient Engagement objective and all of its associated measures as described above. Finally, we are proposing to rename the Public Health and Clinical Data Registry Reporting objective to Public Health and Clinical Data Exchange and require reporting on at least two measures of the MIPS eligible clinician's choice from the following: Immunization Registry Reporting; Syndromic Surveillance Reporting; Electronic Case Reporting;

¹⁸ <https://www.hhs.gov/opioids/about-the-epidemic/index.html>; <https://www.healthit.gov/opioids>.

Public Health Registry Reporting; and Clinical Data Registry Reporting. In addition, we are proposing exclusion criteria for each of these measures.

Finally, we are seeking comment on a potential new measure Health Information Exchange Across the Care Continuum under the Health

Information Exchange objective in which a MIPS eligible clinician would send an electronic summary of care record, or receive and incorporate an electronic summary of care record, for transitions of care and referrals with a health care provider other than a MIPS eligible clinician. The measure would

include health care providers in care settings including but not limited to long term care facilities and post-acute care providers such as skilled nursing facilities, home health, and behavioral health settings.

Table 39 provides a summary of these measures proposals.

TABLE 39—SUMMARY OF PROPOSALS FOR THE PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY OBJECTIVES AND MEASURES FOR THE MIPS PERFORMANCE PERIOD IN 2019

Measure status	Measure
Measures retained—no modifications*.	<ul style="list-style-type: none"> • e-Prescribing.
Measures retained with modifications.	<ul style="list-style-type: none"> • Send a Summary of Care (name proposal—Support Electronic Referral Loops by Sending Health Information). • Provide Patient Access (name proposal—Provide Patients Electronic Access to Their Health Information). • Immunization Registry Reporting. • Syndromic Surveillance Reporting. • Electronic Case Reporting. • Public Health Registry Reporting. • Clinical Data Registry Reporting.
Removed measures	<ul style="list-style-type: none"> • Request/Accept Summary of Care. • Clinical Information Reconciliation. • Patient-Specific Education. • Secure Messaging. • View, Download or Transmit. • Patient-Generated Health Data.
New measures	<ul style="list-style-type: none"> • Query of Prescription Drug Monitoring Program (PDMP). • Verify Opioid Treatment Agreement. • Support Electronic Referral Loops—Receiving and Incorporating Health Information.

* Security Risk Analysis is retained, but not included as a measure under the proposed scoring methodology.

We understand from previous listening sessions that EHR vendors and developers would need time to develop, test and implement new measures, and MIPS eligible clinicians would need time to implement as well as establish and test their processes and workflows. As indicated above and in the discussion of the proposed scoring methodology in section III.H.3.h.(5)(d) of this proposed rule, we are proposing three new measures (Query of PDMP, Verify Opioid Treatment Agreement, and Support Electronic Referral Loops by Receiving and Incorporating Health Information). We are proposing that the Query of PDMP and Verify Opioid Treatment Agreement measures would be optional for the performance period in 2019 and bonus points may be earned for reporting on them. We are proposing that the Support Electronic Referral Loops by Receiving and Incorporating Health Information would be required beginning with the performance period in 2019 with an exclusion available. We are proposing to require the Query of PDMP and Verify Opioid Treatment Agreement measures beginning with the performance period in 2020, and we are seeking public comment on this proposal. The proposals under the Health Information Exchange objective

require only consolidation of existing workflows and actions, while certification criteria and standards remain the same as in the CY 2018 Quality Payment Program final rule (82 FR 53677 through 53678). Therefore, we believe MIPS eligible clinicians could potentially implement this new measure for the performance period in 2019.

(ii) Measure Proposals for the e-Prescribing Objective

Based on our review of the submissions we received through the informal measure submission process described in the preceding section, and considerations of overall agency priorities as discussed below, we are proposing two new measures under the e-Prescribing objective. In the CY 2017 Quality Payment Program final rule, we stated that MIPS eligible clinicians would have the option to include or not include controlled substances in the definition of “permissible prescriptions” at their discretion where feasible and allowable by law in the jurisdiction where they provide care (81 FR 77227). We believe it is important to consider other requirements specific to electronic prescribing of controlled substances for health care providers to take into account and how this may

interact with the proposals under this rulemaking. CMS is committed to combatting the opioid epidemic by making it a top priority for the agency and aligning its efforts with the HHS opioid initiative to combat misuse and promote programs that support treatment and recovery support services. The HHS five-point Opioid Strategy aims to:

- *Improve access to prevention, treatment, and recovery support services* to prevent the health, social, and economic consequences associated with opioid addiction and to enable individuals to achieve long-term recovery;

- *Target the availability and distribution of overdose-reversing drugs* to ensure the provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations;

- *Strengthen public health data reporting and collection* to improve the timeliness and specificity of data and to inform a real-time public health response;

- *Support cutting-edge research* that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective

public health interventions to reduce opioid-related health harms; and

- *Advance the practice of pain management* to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

CMS' strategy includes reducing the risk of opioid use disorders, overdoses, inappropriate prescribing practices and drug diversion. We have identified two new measures which align with the broader HHS efforts to increase the use of PDMPs to reduce inappropriate prescriptions, improve patient outcomes and promote more informed prescribing practices.

We are proposing to add two new measures to the e-Prescribing objective that are based on electronic prescriptions for controlled substances (EPCS): Query of PDMP; and Verify Opioid Treatment Agreement. These measures build upon the meaningful use of CEHRT as well as the security of electronic prescribing of Schedule II controlled substances while preventing diversion. For both measures, we are proposing to define opioids as Schedule II controlled substances under 21 CFR 1308.12, as they are recognized as having a high potential for abuse with potential for severe psychological or physical dependence. We are also proposing to apply the same policies for the existing e-Prescribing measure to both the Query of PDMP and Verify Opioid Treatment Agreement measures, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy. MIPS eligible clinicians have the option to include or exclude controlled substances in the e-Prescribing measure denominator as long as they are treated uniformly across patients and all available schedules and in accordance with applicable law (81 FR 77227). However, because the intent of these two new measures is to improve prescribing practices for controlled substances, MIPS eligible clinicians would have to include Schedule II opioid prescriptions in the numerator and denominator or claim the applicable exclusion. Additionally, the intent of the proposed measures is not to dissuade the prescribing or use of opioids for patients with medical diagnoses or conditions that benefit from their use, such as patients diagnosed with cancer or those receiving hospice. We seek comment on the impact that implementing this measure could have on patients who receive opioids due to medical diagnoses such as cancer or receiving

hospice care as well as treatment of patients under a program involving substance abuse education, treatment, or prevention under 42 CFR part 2. Additionally, we seek comment on the federal and state statutory and regulatory requirements that may impact implementation of the Query of PDMP and Verify Opioid Treatment Agreement measures.

In the event we finalize the new scoring methodology that we are proposing in section III.H.3.h.(5)(d) of this proposed rule, MIPS eligible clinicians who claim the exclusion under the existing e-Prescribing measure would automatically receive an exclusion for all three of the measures under the e-Prescribing objective; they would not have to also claim exclusions for the other two measures, Query of PDMP and Verify Opioid Treatment Agreement.

In the event we do not finalize the new scoring methodology proposed in section III.H.3.h.(5)(d) of this proposed rule, but we do finalize the proposed measures of Query of PDMP and Verify Opioid Treatment Agreement under the e-Prescribing objective, we propose to include them under the bonus score with each measure being worth 5 percentage points, but we would not include exclusion criteria as reporting would be optional under the scoring methodology finalized in previous rulemaking (81 FR 77216 through 77227 and 82 FR 53663 through 53664). We believe these measures should be part of the bonus score because not all MIPS eligible clinicians are able to prescribe controlled substances, and therefore these measures may not be applicable to them. Additionally, in the event we do not finalize the proposed scoring methodology, we would retain the existing e-Prescribing measure (with its exclusion) as a base score requirement.

(A) Proposed Measure: Query of Prescription Drug Monitoring Program (PDMP)

A PDMP is an electronic database that tracks prescriptions of controlled substances at the State level. PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Querying the PDMP is important for tracking the prescribed controlled substances and improving prescribing practices. The ONC, Centers for Disease Control and Prevention (CDC), Department of Justice (DOJ) and Substance Abuse and Mental Health Services Administration (SAMHSA) have had integral roles in the integration

and expansion of PMDPs with health information technology systems. For example, the ONC and SAMHSA collaboratively led the "Enhancing Access" project to improve health care provider access to PDMP data utilizing health IT.¹⁹ Likewise, the CDC conducted a process and outcome evaluation of the PDMP EHR Integration and Interoperability Expansion (PEHRIIE) program funded by SAMHSA for nine states between FY 2012 and 2016. The PEHRIIE program goals were to integrate PDMPs into health IT and improve the comprehensiveness of PDMPs through initiating and/or improving interstate data exchange.²⁰ In addition, the Bureau of Justice Assistance's Harold Rogers Prescription Monitoring Program supports Prescription Drug Monitoring Program Information Exchange (PMIX) through funding, the goal of PMIX is to help states implement a cost-effective solution to facilitate interstate data sharing among PDMPs.²¹ Integration of the PDMP with health information technology systems supports improves access to PDMP data, minimizes changes to current workflow and overall burden and optimizes prescribing practices. The intent of the Query of the PDMP measure is to build upon the current PDMP initiatives from Federal partners focusing on prescriptions generated and dispensing of opioids.

Proposed Measure Description: For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law.

CMS recognizes both the utility and value of addressing PDMP EHR integration and further recognizes the majority of states mandate use of State prescription monitoring programs (PMPs) requiring prescribers/dispensers to access PMP.²² According to the CDC, State-level policies that enhance PDMPs or regulate pain clinics helped several states drive down opioid prescriptions and overdose deaths.²³ We are also further aware of the varying integration

¹⁹ <https://www.healthit.gov/PDMP> and https://www.healthit.gov/sites/default/files/work_group_document_integrated_paper_final_0.pdf.

²⁰ https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf.

²¹ <https://www.bja.gov/funding/Category-5-awards.pdf>.

²² <http://www.namsdl.org/library/14D3122C-96F5-F53E-E8F23E906B4DE09D/>.

²³ <https://www.cdc.gov/drugoverdose/policy/successes.html>.

approaches underway including efforts to integrate a state PDMP into a health information exchange or EHR or other efforts to enhance a user interface of some type, such as risk assessment tools or red flags. We note federal evaluation resources available to inform integration efforts²⁴ and believe integration is critical for enhancing health care provider workflow, access to critical PDMP data, and improving clinical care including prescription management.

We are proposing that the query of the PDMP for prescription drug history must be conducted prior to the electronic transmission of the Schedule II opioid prescription. MIPS eligible clinicians would have flexibility to query the PDMP using CEHRT in any manner allowed under their State law.

Although the query of the PDMP may currently be burdensome for some MIPS eligible clinicians as part of their current workflow practice, we believe querying the PDMP is beneficial to optimal prescribing practices and foresee progression toward fully automated queries of the PDMP building upon the current initiatives at the State level.

We are proposing to include in this measure all permissible prescriptions and dispensing of Schedule II opioids regardless of the amount prescribed during an encounter in order for MIPS eligible clinicians to identify multiple health care provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities. We request comment on these policy proposals, including whether additional queries should be performed and under which circumstances. In addition we seek comment on whether the query should have additional constraints concerning when it should be performed.

Denominator: Number of Schedule II opioids electronically prescribed using CEHRT by the MIPS eligible clinician during the performance period.

Numerator: The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law. A numerator of at least one is required to fulfill this measure.

Exclusion (beginning in 2020): Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period. We

propose that the exclusion criteria would be limited to prescriptions of Schedule II opioids as the measure action is limited to prescriptions of Schedule II opioids only and does not include any other types of electronic prescriptions. We are also requesting comment on the proposed exclusion criteria and whether there are circumstances which may justify other exclusions for the Query of PDMP measure and what those circumstances might be including medical diagnoses such as cancer or patients under care of hospice.

We also understand that PDMP integration is not currently in widespread use for CEHRT, and many MIPS eligible clinicians may require additional time and workflow changes at the point of care before they can meet this measure without experiencing significant burden. For instance, many MIPS eligible clinicians will likely need to manually enter the data into CEHRT to document the completion of the query of the PDMP action. In addition, some MIPS eligible clinicians may also need to conduct manual calculation of the measure. Even for those MIPS eligible clinicians that have achieved successful integration of a PDMP with their EHR, this measure may not be machine calculable, for instance, in cases where the MIPS eligible clinician follows a link within the EHR to a separate PDMP system. For the purposes of meeting this measure, we also understand that there is no existing certification criteria for the query of a PDMP. However, we believe that the use of structured data captured in the CEHRT can support querying a PDMP through the broader use of health IT. We seek public comment on whether ONC should consider adopting standards and certification criteria to support the query of a PDMP, and if such criteria were to be adopted, on what timeline should CMS require their use to meet this measure.

The NCPDP SCRIPT 2017071 standard for e-prescribing is now available and can help to support PDMP and EHR integration. We are seeking public comment, especially from health care providers and health IT developers on whether they believe use of this standard can support MIPS eligible clinicians seeking to report on this measure, and whether HHS should encourage use of this standard through separate rulemaking.

We seek comment on the challenges associated with querying the PDMP with and without CEHRT integration and whether this proposed measure should require certain standards,

methods or functionalities to minimize burden.

In including EPCS as a component of the measure as proposed, we acknowledge and seek input on perceived and real technological barriers as part of its effective implementation including but not limited to input on two-factor authentication and on the effective and appropriate uses of technology, including the use of telehealth modalities to support established patient and health care provider relationships subsequent to in-person visit(s) and for prescribing purposes.

In the event we do not finalize the proposed scoring methodology, we are proposing MIPS eligible clinicians must report at least one prescription in the numerator to report on this new measure and earn points towards the bonus score. We believe a threshold of at least one prescription is appropriate because varying State laws related to integration of the PDMP into CEHRT can lead to differing standards for querying.

We are also proposing that in order to meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(a)(10)(ii) and (b)(3).

(B) Proposed Measure: Verify Opioid Treatment Agreement

The intent of this measure is for MIPS eligible clinicians to identify whether there is an existing opioid treatment agreement when they electronically prescribe a Schedule II opioid using CEHRT if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days. We believe seeking to identify an opioid treatment agreement will further efforts to coordinate care between health care providers and foster a more informed review of patient therapy. The intent of the treatment agreement is to clearly outline the responsibilities of both patient and MIPS eligible clinician in the treatment plan. Such a treatment plan can be integrated into care coordination and care plan activities and documents as discussed and agreed upon by the patient and MIPS eligible clinician. An opioid treatment agreement is intended to support and to enable further coordination and the sharing of substance use disorder (SUD) data with consent, as may be required of the individual.

According to the American Journal of Psychiatry article *Prescription Opioid Misuse, Abuse, and Treatment in the*

²⁴ https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf.

United States: An Update,²⁵ patient and health care provider treatment agreements are part of the recommendations to enhance efforts to prevent opioid abuse per the Office of the National Drug Control Policy's National Drug Control Strategy.²⁶ The article further indicates that the treatment agreement can be beneficial as it provides clear information for the agreed upon pain management plan, preventing misconceptions.

An article in *Pain Medicine*, *Universal Precautions in Pain Medicine: A Rational Approach to the Treatment of Chronic Pain* also includes treatment agreements as part of the "Ten Steps of Universal Precautions in Pain Medicine" which are stated to be recommended starting points for discussion in the treatment of chronic pain.²⁷

We also understand from stakeholder feedback during listening sessions that there are varied opinions regarding opioid treatment agreements amongst health care providers. Some are supportive of their use, indicating that treatment agreements are an important part of the prescription of opioids for pain management, and help patients understand their role and responsibilities for maintaining compliance with terms of the treatment. Other health care providers object to their use citing ethical concerns, and creation of division and trust issues in the health care provider-patient relationship. Other concerns stem from possible disconnect between the language and terminology used in the agreement and the level of comprehension on the part of the patient. Because of the debate among practitioners, we request comment on the challenges this proposed measure may create for MIPS eligible clinicians, how those challenges might be mitigated, and whether this measure should be included as part of the Promoting Interoperability performance category. We also acknowledge challenges related to prescribing practices and multiple State laws which may present barriers to the uniform

implementation of this proposed measure. We are seeking public comment on the challenges and concerns associated with opioid treatment agreements and how they could impact the feasibility of the proposal.

Proposed Measure Description: For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the MIPS eligible clinician seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient's electronic health record using CEHRT.

We are proposing this measure would include all Schedule II opioids prescribed for a patient electronically using CEHRT by the MIPS eligible clinician during the performance period, as well as any Schedule II opioid prescriptions identified in the patient's medication history request and response transactions during a 6-month look-back period, where the total number of days for which a Schedule II opioid was prescribed for the patient is at least 30 days.

There also may be MIPS eligible clinician burdens specific to identifying the existence of a treatment agreement which could require additional time and changes to existing workflows, determining what constitutes a treatment agreement due to a lack of a definition, standard or electronic format and manual calculation of the measure. In addition, limitations in the completeness of care team information may limit the ability of a MIPS eligible clinician to identify all potential sources for querying and obtaining information on a treatment agreement for a specific patient. There are currently pilots in development focused on increasing connectivity and data exchange among health care providers to better integrate behavioral health information, for instance, pilots taking place as part of the federal Demonstration Program for Certified Community Behavioral Health Clinics (CCBHC)²⁸ includes criteria on how CCBHCs should use health IT to coordinate services and track data on quality measures. Participants in such pilots would potentially have the means necessary to leverage health IT connectivity to query behavioral health data resources and health providers within their region to identify the existence of an opioid treatment

agreement and to successfully integrate patient information from the hospital stay into the care plan for the patient. We seek comment on other similar pathways to facilitate the identification and exchange of treatment agreements and opioid abuse treatment planning.

We are proposing the 6-month look-back period would begin on the date on which the MIPS eligible clinician electronically transmits their Schedule II opioid prescription using CEHRT. For example, all of the following prescriptions would be counted for this measure: A Schedule II opioid electronically prescribed for a patient for a duration of five days by the MIPS eligible clinician using CEHRT during the performance period, and four prior prescriptions for any Schedule II opioid prescribed by another health care provider (each for a duration of seven days) as identified in the patient's medication history request and response transactions during the 6-month period preceding the date on which the MIPS eligible clinician electronically transmits their Schedule II opioid prescription using CEHRT. In this example, the total number of days for which a Schedule II opioid was prescribed for the patient would equal 33 cumulative days.

We are proposing a 6-month look-back period to identify more egregious cases of potential overutilization of opioids and to cover timeframes for use outside the performance period. In addition, we are proposing that the 6-month look-back period would utilize at a minimum the industry standard NCDIC SCRIPT v10.6 medication history request and response transactions codified at § 170.205(b)(2)). As ONC has stated (80 FR 62642), adoption of the requirements for NCDIC SCRIPT v10.6 does not preclude developers from incorporating and using technology standards or services not required by regulation in their health IT products.

We are not proposing to define an opioid treatment agreement as a standardized electronic document; nor are we proposing to define the data elements, content structure, or clinical purpose for a specific document to be considered a "treatment agreement." For this measure, we are seeking comment on what characteristics should be part of an opioid treatment agreement including data, content and clinical purpose into CEHRT, including which functionalities could be utilized to accomplish this. We note that a variety of standards available in CEHRT might support the electronic exchange of opioid abuse related treatment data, such as use of the Consolidated Clinical

²⁵ Brady, K.T., McCauley, J.L., Back, S.E. Prescription Opioid Misuse, Abuse, and Treatment in the United States: An Update, *American Journal of Psychiatry*, Volume 173, Issue 1, January 01, 2016, pp. 18–26. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4782928/>.

²⁶ <https://obamawhitehouse.archives.gov/ondcp/policy-and-research/ndcs>.

²⁷ Gourlay, D.L., Heit, H.A., Almahrezi, A. "Universal Precautions in Pain Medicine: A Rational Approach to the Treatment of Chronic Pain." *Pain Medicine*, Volume 6, Issue 2, 1 March 2005, pp. 107–112. Available at <https://academic.oup.com/painmedicine/article/6/2/107/1819946>.

²⁸ <https://www.samhsa.gov/section-223>.

Document Architecture (CCDA) care plan template that is currently optional in CEHRT. We are also seeking comment on methods or processes for incorporation of the treatment agreement into CEHRT, including which functionalities could be utilized to accomplish this task. We seek comment on whether there are specific data elements that are currently standardized that should be incorporated via reconciliation and if the “patient health data capture” functionality (45 CFR 170.315(e)(3)) could be used to incorporate a treatment plan that is not a structured document with structured data elements.

Denominator: Number of unique patients for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period and the total duration of Schedule II opioid prescriptions is at least 30 cumulative days as identified in the patient’s medication history request and response transactions during a 6-month look-back period.

Numerator: The number of unique patients in the denominator for whom the MIPS eligible clinician seeks to identify a signed opioid treatment agreement and, if identified, incorporates the agreement in CEHRT. A numerator of at least one is required to fulfill this measure.

Exclusion (beginning in 2020): Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period.

We propose that the exclusion criteria would be limited to prescriptions of Schedule II opioids as the measure action is limited to electronic prescriptions of Schedule II opioids only and does not include any other types of electronic prescriptions.

We are requesting comment on the proposed exclusion criteria and whether there are additional circumstances that should be added to the exclusion criteria and what those circumstances might be including medical diagnoses such as cancer or patients under care of hospice.

We are seeking comment on whether these types of agreements could create a burden on clinicians and patients, particularly clinicians who serve patients with cancer or those practicing in hospice, as well as the patients they serve.

In the event we do not finalize the proposed scoring methodology, we are proposing MIPS eligible clinicians must report at least one unique patient in the numerator to report on this new measure and earn points towards the

bonus score. We believe a threshold of at least one unique patient is appropriate to account for the varying support for the use of opioid treatment agreements and acknowledging that not all patients who receive at least 30 cumulative days of Schedule II opioids would have a treatment agreement in place. We also note there are medical diagnoses and conditions that could necessitate prescribing Schedule II opioids for a cumulative period of more than 30 days including medical diagnoses such as cancer or care under hospice.

We also are proposing that, in order to meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at §§ 170.315(a)(10) and (b)(3) and 170.205(b)(2).

As discussed above, we recognize that many health care providers are only beginning to adopt electronic prescriptions for controlled substances (EPCS) at this time. While we have proposed two new measures which combine EPCS with other actions, we request comment on whether stakeholders would be interested in a measure focused only on the number of Schedule II opioids prescribed and the successful use of EPCS for permissible prescriptions electronically prescribed. We seek comment about the feasibility of such a measure, and whether stakeholders believe this would help to encourage broader adoption of EPCS.

(iii) Measure Proposals for the Health Information Exchange Objective

The Health Information Exchange measures for MIPS eligible clinicians hold particular importance because of the role they play within the care continuum. In addition, these measures encourage and leverage interoperability on a broader scale and promote health IT-based care coordination. However, through our review of the existing measures, we determined that we could potentially improve the measures to further reduce burden and better focus the measures on interoperability in health care provider to health care provider exchange. Such modifications would address a number of concerns raised by stakeholders including:

- Supporting the implementation of effective health IT supported workflows based on a specific organization’s needs;
- Reducing complexity and burden associated with the manual tracking of workflows to support health IT measures; and
- Emphasizing within these measures the importance of using health IT to support closing the referral loop to improve care coordination.

We believe we can potentially improve the existing Health Information Exchange measures to streamline measurement, remove redundancy, reduce complexity and burden, and address stakeholders’ concerns about the focus and impact of the measures on the interoperable use of health IT.

We are proposing several changes to the current measures under the Health Information Exchange objective. First, we propose to change the name of the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information. We also propose to remove the Clinical Information Reconciliation measure and combine it with the Request/Accept Summary of Care measure to create a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information. This proposed new measure would include actions from both the Request/Accept Summary of Care measure and Clinical Information Reconciliation measure.

In the event we do not finalize a new scoring methodology as proposed in section III.H.3. h.(5)(d) of this proposed rule, we would maintain the existing Health Information Exchange objective, measures and reporting requirements as finalized in the CY 2018 Quality Payment Program final rule at 82 FR 53674 through 53680.

(A) Proposed Modifications to the Send a Summary of Care Measure

We are proposing to change the name of the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information measure, to better reflect the emphasis on completing the referral loop and improving care coordination.

Through public comment and stakeholder correspondence, we have become aware that in the health care industry there is some misunderstanding of the scope of transitions and referrals which must be included in the denominator of this measure. In the event that a MIPS eligible clinician is the recipient of a transition of care or referral, and subsequent to providing care the MIPS eligible clinician transitions or refers the patient back to the referring provider of care, this transition of care should be included in the denominator of the measure for the MIPS eligible clinician. We expect this will help build upon the current provider to provider communication via electronic exchange of summary of care records created by CEHRT required under this measure, further promote interoperability and care coordination with additional health

care providers, and prevent redundancy in creation of a separate measure.

In the past, stakeholders have raised concerns that the summary care records shared according to the CCDA standard included excessive information not relevant to immediate care needs, which increased burden on health care providers. Under the ONC Health IT Certification Program 2015 Edition, CEHRT must have the capability to exchange all of the information in the CCDS as part of a summary care record structured according to the CCDA standard. We previously finalized in the final rule titled “Medicare and Medicaid Programs Electronic Health Record Incentive Program—Stage 2: Health Information Technology, Standards Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology” (hereafter referred to as the “Stage 2 final rule”) (77 FR 53991 through 53993) that health care providers must transmit all of the CCDS information as part of this summary care record, if known, and that health care providers must always transmit information about the problem list, medications, and medication allergies, or validate that this information is not known.

As finalized in the “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; Final Rule” (hereafter referred to as the “2015 EHR Incentive Programs final rule” (80 FR 62852 through 62861), our policy allows health care providers to constrain the information in the summary care record to support transitions of care. For instance, we encouraged health care providers to send a list of items that he or she believes to be pertinent and relevant to the patient’s care, rather than a list of all problems, whether active or resolved, that have ever populated the problem list. While a current problem list must always be included, the health care provider can use his or her judgment in deciding which items historically present on the problem list, medical history list (if it exists in CEHRT), or surgical history list are relevant given the clinical circumstances.

We also wish to encourage MIPS eligible clinicians to use the document template available within the CCDA which contains the most clinically relevant information required by the receiver. Accordingly, we are proposing that MIPS eligible clinicians may use any document template within the

CCDA standard for purposes of the measures under the Health Information Exchange objective. While a MIPS eligible clinician’s CEHRT must be capable of sending the full CCDA upon request, we believe this additional flexibility will help support clinicians’ efforts to ensure the information supporting a transition is relevant.

For instance, when the MIPS eligible clinician is referring to another health care provider the recommended document is the “Referral Note” which is designed to communicate pertinent information from a MIPS eligible clinician who is requesting services of another health care provider of clinical or non-clinical services. When the receiving health care provider sends back the information, the most relevant CCDA document template may be the “Consultation Note,” which is generated by a request from a clinician for an opinion or advice from another clinician. While the 2015 Edition transition of care certification criterion only requires testing to the Continuity of Care Document and Referral Note document templates, we are proposing to allow MIPS eligible clinicians the flexibility to use additional CCDA templates most appropriate to their clinical workflows. Clinicians would need to work with their health IT developer to determine appropriate technical workflows and implementation. For more information about the CCDA and associated templates, see http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG_CCDA_CLINNOTES_R1_DSTUR2.1_2015AUG.zip.

In the event we do not finalize a new scoring methodology as proposed in section III.H.3.h.(5)(d), we would maintain the current Promoting Interoperability performance category objectives, measures and reporting requirements as finalized in previous rulemaking. MIPS eligible clinicians would be required to report the Send a Summary of Care measure as part of the base score as finalized in previous rulemaking (82 FR 53674 through 53680).

(B) Proposed Removal of the Request/Accept Summary of Care Measure

We are proposing to remove the Request/Accept Summary of Care measure based on our analysis of the existing measure and in response to stakeholder input.

Through review of implementation practices based on stakeholder feedback, we believe that the existing Request/Accept Summary of Care measure is not feasible for machine calculation in the majority of cases. The intent of the

measure is to identify when MIPS eligible clinicians are engaging with other providers of care or care team members to obtain up-to-date patient health information and to subsequently incorporate relevant data into the patient record. However, stakeholders have noted the measure specification does not effectively further this purpose. Specifically, the existing measure specification results in unintended consequences where health care providers implement either:

(1) A burdensome workflow to document the manual action to request or obtain an electronic record, for example, clicking a check box to document each phone call or similar manual administrative task, or

(2) A workflow which is limited to only querying internal resources for the existence of an electronic document.

Neither of these two implementation options is desirable when the intent of the measure is to incentivize and encourage health care providers to implement effective workflows to identify, receive, and incorporate patient health information from other health care providers into the patient record.

In addition, our analysis identified that the definition of incorporate within the Request/Accept Summary of Care measure is insufficient to ensure an interoperable result. When this measure was initially finalized in the 2015 EHR Incentive Programs final rule at 80 FR 62860, we did not define “incorporate” as we believed it would vary amongst health care provider’s workflows, patient population and the referring health care provider. In addition, we noted that the information could be included as an attachment, as a link within the EHR, as imported structured data or reconciled within the record and not exclusively performed through use of CEHRT. Further, stakeholder feedback highlights the fact that the requirement to incorporate data is insufficiently clear regarding what data must be incorporated.

Our intention was that “incorporate” would relate to the workflows undertaken in the process of clinical information reconciliation further defined in the Clinical Information Reconciliation measure (80 FR 62852 through 62862). Taken together, the three measures under the Health Information Exchange objective were intended to support the referral loop through sending, receiving, and incorporating patient health data into the patient record. However, stakeholder feedback on the measures suggests that the separation between receiving and reconciling patient health

information is not reflective of clinical and care coordination workflows. Further, stakeholders noted, that when approached separately, the incorporate portion of the Request/Accept Summary of Care measure is both inconsistent with and redundant to the Clinical Information Reconciliation measure which causes unnecessary burden and duplicative measure calculation.

(C) Proposed Removal of the Clinical Information Reconciliation Measure

We are proposing to remove the Clinical Information Reconciliation measure to reduce redundancy, complexity, and MIPS eligible clinician burden.

We believe the Clinical Information Reconciliation measure is redundant in regard to the requirement to “incorporate” electronic summaries of care in light of the requirements of the Request/Accept Summary of Care measure. In addition, the measure is not fully health IT based as the exchange of health care information is not required to complete the measure action and the measure specification is not limited to only the reconciliation of electronic information in health IT supported workflows. We stated in the 2015 EHR Incentive Programs final rule at 80 FR 62861 that the clinical information reconciliation process could involve both automated and manual reconciliation to allow the receiving health care provider to work with both electronic data received as well as the patient to reconcile their health information. Further, stakeholder feedback from hospitals, clinicians, and health IT developers indicates that because the measure is not fully based on the use of health IT to meet the measurement requirements, health care providers must engage in burdensome tracking of manual workflows. While the overall activity of clinical information reconciliation supports quality patient care and should be a part of effective clinical workflows, the process to record and track each individual action places unnecessary burden on MIPS eligible clinicians.

(D) Proposed New Measure: Support Electronic Referral Loops by Receiving and Incorporating Health Information

We are proposing to add the following new measure for inclusion in the Health Information Exchange objective: Support Electronic Referral Loops by Receiving and Incorporating Health Information. This measure would build upon and replace the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures.

Proposed name of measure and description: Support Electronic Referral Loops by Receiving and Incorporating Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, medication allergy, and current problem list.

We are proposing to combine two existing measures, the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure, in this new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to focus on the exchange of health care information as the current Clinical Information Reconciliation measure is not reliant on the exchange of health care information to complete the measure action. We are not proposing to change the actions associated with the existing measures; rather, we are proposing to combine the two measures to focus on the exchange of the health care information, reduce administrative burden, and streamline and simplify reporting.

CMS and ONC worked together to define the following for this measure:

Denominator: Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.

Numerator: The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient’s medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy—Review of the patient’s known medication allergies; and (3) Current Problem List—Review of the patient’s current and active diagnoses.

Exclusion: Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period.

We are requesting comment on the proposed exclusion criteria and whether there are additional circumstances that should be added to the exclusion criteria and what those circumstances might be.

For the proposed measure, the denominator would increment on the receipt of an electronic summary of care record after the MIPS eligible clinician engages in workflows to obtain an electronic summary of care record for a transition, referral or patient encounter in which the MIPS eligible clinician has never before encountered the patient. The numerator would increment upon completion of clinical information reconciliation of the electronic summary of care record for medications, medication allergies, and current problems. The MIPS eligible clinician would no longer be required to manually count each individual non-health-IT-related action taken to engage with other providers of care and care team members to identify and obtain the electronic summary of care record. Instead, the proposed measure would focus on the result of these actions when an electronic summary of care record is successfully identified, received, and reconciled with the patient record. We believe this approach would allow MIPS eligible clinicians to determine and implement appropriate workflows supporting efforts to receive the electronic summary of care record consistent with the implementation of effective health IT information exchange at an organizational level.

Finally, we are proposing to apply our existing policy for cases in which the MIPS eligible clinician determines no update or modification is necessary within the patient record based on the electronic clinical information received, and the MIPS eligible clinician may count the reconciliation in the numerator without completing a redundant or duplicate update to the record. We welcome public comment on methods by which this specific action could potentially be electronically measured by the MIPS eligible clinician’s health IT system—such as incrementing on electronic signature or approval by an authorized health care provider—to mitigate the risk of burden associated with manual tracking of the action, such as having to click check boxes.

We welcome public comment on these proposals. We are seeking comment on methods and approaches to quantify the reduction in burden for MIPS eligible clinicians implementing streamlined workflows for this proposed health IT-based measure. We also are seeking comment on the impact these

proposed modifications may have for health IT developers in updating, testing, and implementing new measure calculations related to these proposed changes. Specifically, we seek comment on whether ONC should require developers to recertify their EHR technology as a result of the changes proposed, or whether they should be able to make the changes and engage in testing without recertification, and on the appropriate timeline for such requirements factoring in the proposed continuous 90 day performance period within the calendar year for clinicians. Finally, we are seeking comment on whether this proposed new measure that combines the Request/Accept Summary of Care and Clinical Information Reconciliation measures should be adopted, or whether either or both of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures should be retained in lieu of this proposed new measure.

In the event we finalize the new scoring methodology we are proposing in section III.H.3.h.(5)(d) of this proposed rule, an exclusion would be available for MIPS eligible clinicians who could not implement the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure for a performance period in CY 2019.

In the event we do not finalize the proposed scoring methodology, we would maintain the current Promoting Interoperability performance category objectives, measures and reporting requirements as finalized in previous rulemaking. MIPS eligible clinicians would be required to report the Request/Accept Summary of Care measure as part of the base score and the Clinical Information Reconciliation measure would remain as part of the performance score as finalized in previous rulemaking (82 FR 53674 through 53680).

We also are proposing that, in order to meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at § 170.315(b)(1) and (2).

(iv) Measure Proposals for the Provider to Patient Exchange Objective

The Provider to Patient Exchange objective for MIPS eligible clinicians builds upon the goal of improved access and exchange of patient data, patient centered communication and coordination of care using CEHRT. We are proposing a new scoring methodology in section III.H.3.h.(5)(d) of this proposed rule, under which we are proposing to rename the Patient

Electronic Access objective to Provider to Patient Exchange, remove the Patient-Specific Education measure and rename the Provide Patient Access measure to Provide Patients Electronic Access to Their Health Information. In addition, we are proposing to remove the Coordination of Care through Patient Engagement objective and all associated measures. The existing Promoting Interoperability performance category Patient Electronic Access objective includes two measures and the existing Coordination of Care through Patient Engagement objective includes three measures.

We reviewed the Promoting Interoperability performance category requirements and determined that these proposals could reduce program complexity and burden and better focus on leveraging the most current health IT functions and standards for patient flexibility of access and exchange of information.

We are proposing the Provider to Patient Exchange objective would include one measure, the existing Provide Patient Access measure, which are proposing to rename to Provide Patients Electronic Access to Their Health Information.

In the event we do not finalize the proposed scoring methodology in III.H.3.(5)(c), we would maintain the current Promoting Interoperability performance category objectives, measures and reporting requirements as finalized in previous rulemaking. MIPS eligible clinicians would be required to report the Provide Patient Access measure as part of the base score under the Patient Electronic Access objective, and the Patient-Specific Education measure would remain as part of the performance score as finalized in previous rulemaking (82 FR 53674 through 53680). The Coordination of Care Through Patient Engagement objective and its associated measures (VDT, Secure Messaging, and Patient-Generated Health Data) would remain as part of the performance score as finalized in previous rulemaking (82 FR 53674 through 53680).

(A) Proposed Modification To Provide Patient Access Measure

We are proposing to change the name of the Provide Patient Access measure to Provide Patients Electronic Access to Their Health Information measure to better reflect the emphasis on patient engagement in their health care and patient's electronic access of their health information through use of APIs.

We propose to change the measure name to emphasize electronic access of patient health information as opposed to

use of paper based actions and limit the focus to only health IT solutions to encourage adoption and innovation in use of CEHRT (80 FR 62783 through 62784). In addition, we are committed to promoting patient engagement with their healthcare information and ensuring access in an electronic format.

(B) Proposed Removal of the Patient-Generated Health Data Measure

We are proposing to remove the Patient-Generated Health Data (PGHD) measure to reduce complexity and focus on the goal of using advanced EHR technology and functionalities to advance interoperability and health information exchange.

As finalized in the 2015 EHR Incentive Programs final rule at 80 FR 62851, the measure is not fully health IT based as we did not specify the manner in which health care providers would incorporate the data received. Instead, we finalized that health care providers could work with their EHR developers to establish the methods and processes that work best for their practice and needs. We indicated that this could include incorporation of the information using a structured format (such as an existing field in the EHR or maintaining an isolation between the data and the patient record such as incorporation as an attachment, link or text reference which would not require the advanced use of CEHRT). While we continue to believe that incorporating this data is valuable, we are prioritizing only those actions which are completed electronically using certified health IT.

(C) Proposed Removal of the Patient-Specific Education Measure

We are proposing to remove the Patient-Specific Education measure as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from their progress on current program priorities.

The Patient-Specific Education measure was finalized as a performance score measure for MIPS eligible clinicians in the CY 2017 Quality Payment Program final rule with the intent of improving patient health, increasing transparency and engaging patients in their care (81 FR 77228 through 77237).

We believe that the Patient-Specific Education measure does not align with the current emphasis of the Promoting Interoperability performance category to increase interoperability, or reduce burden for MIPS eligible clinicians. In addition to not including interoperability as a core focus, stakeholders have indicated that this measure does not capture many of the

innovative activities around providing patient education, for instance new approaches to integrating patient education within clinical decision support modules. As a result of this lack of alignment, this measure could potentially increase clinician burden.

(D) Proposed Removal of the Secure Messaging Measure

We are proposing to remove the Secure Messaging measure as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from MIPS eligible clinicians' progress on current program priorities.

The Secure Messaging measure was finalized in the CY 2017 Quality Payment Program final rule with the intent to build upon the policy goals of Stage 2 under the EHR Incentive Programs of using CEHRT for health care provider-patient communication (81 FR 77227 through 77236). As outlined above, we believe that the Secure Messaging measure does not align with the current emphasis of the Promoting Interoperability performance category to increase interoperability or reduce burden for MIPS eligible clinicians. In addition, we believe there is burden associated with tracking secure messages, including the unintended consequences of workflows designed for the measure rather than for clinical and administrative effectiveness.

(E) Proposed Removal of the View, Download or Transmit Measure

We are proposing to remove the View, Download or Transmit measure as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from their progress on current program priorities.

We received MIPS eligible clinician and stakeholder feedback through correspondence, public forums, and listening sessions indicating there is ongoing concern with measures which require patient action for successful submission. We have noted that data analysis on the patient action measures supports stakeholder concerns that barriers exist which impact a clinician's ability to meet them. Stakeholders have indicated that successful submission of the measure is reliant upon the patient, who may face barriers to access which are outside a clinician's control.

After additional review, we note that successful performance predicated solely on a patient's action has inadvertently created burdens to MIPS eligible clinicians and detracts from progress on Promoting Interoperability measure goals of focusing on patient

care, interoperability and leveraging advanced use of health IT. Therefore, we propose to remove the View, Download or Transmit measure.

(v) Proposed Modifications to the Public Health and Clinical Data Registry Reporting Objective and Measures

In connection with the scoring methodology proposed in section III.H.3.h.(5)(d) of this proposed rule, we are proposing changes to the Public Health and Clinical Data Registry Reporting objective and five associated measures.

We believe that public health reporting through EHRs will extend the use of electronic reporting solutions to additional events and care processes, increase timeliness and efficiency of reporting and replace manual data entry.

We are proposing to change the name of the objective to Public Health and Clinical Data Exchange and are proposing exclusions for each of the associated measures.

Under the new scoring methodology proposed in section III.H.3.h.(5)(d) of this proposed rule, we are proposing that a MIPS eligible clinician would be required to submit two of the measures of the clinician's choice from the five measures associated with the objective: Immunization Registry Reporting, Syndromic Surveillance Reporting, Electronic Case Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting.

In prior rulemaking, we recognized the goal of increasing interoperability through public health registry exchange of data (80 FR 62771). We continue to believe that public health reporting is valuable in terms of health information exchange between MIPS eligible clinicians and public health and clinical data registries. For example, when immunization information is directly exchanged between EHRs and registries, patient information may be accessed by all of a patient's health care providers for improved continuity of care and reduced health care provider burden, as well as supporting population health monitoring.

We are also proposing exclusion criteria for each of the Public Health and Clinical Data Exchange measures beginning with the performance period in 2019. Under the scoring methodology for the Promoting Interoperability performance category for the performance period in 2018 (82 FR 53676 through 53677), the measures associated with the Public Health and Clinical Data Registry Reporting objective are not required for the base score, and thus we did not establish

exclusion criteria for them. However, we understand that some MIPS eligible clinicians may not be able to report to public health agencies or clinical data registries due to their scope of practice. For example, we noted in the CY 2018 Quality Payment Program final rule (82 FR 53663) that there are MIPS eligible clinicians who lack access to immunization registries or do not administer immunizations. Also, we noted in the 2017 Quality Payment Program final rule (81 FR 77236) few jurisdictions accept syndromic surveillance from non-urgent care EPs. Therefore, we are proposing the following measure exclusions based on the exclusions finalized in previous rulemaking under the EHR Incentive Programs (80 FR 62862 through 62871).

Measure: Immunization Registry Reporting.

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Immunization Registry Reporting measure if the MIPS eligible clinician:

1. Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period.
2. Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period.
3. Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.

Measure: Syndromic Surveillance Reporting.

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Syndromic Surveillance Reporting measure if the MIPS eligible clinician:

1. Is not in a category of health care providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system.
2. Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the performance period.
3. Operates in a jurisdiction where no public health agency has declared

readiness to receive syndromic surveillance data from MIPS eligible clinicians as of 6 months prior to the start of the performance period.

Measure: Electronic Case Reporting.

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Electronic Case Reporting measure if the MIPS eligible clinician:

1. Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period.
2. Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period.
3. Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period.

Measure: Public Health Registry Reporting.

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Public Health Reporting measure if the MIPS eligible clinician:

1. Does not diagnose or directly treat any disease or condition associated with a public health registry in the MIPS eligible clinician's jurisdiction during the performance period.
2. Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period.
3. Operates in a jurisdiction where no public health registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic

registry transactions as of 6 months prior to the start of the performance period.

Measure: Clinical Data Registry Reporting.

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Clinical Data Registry Reporting measure if the MIPS eligible clinician:

1. Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the performance period.
2. Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period.
3. Operates in a jurisdiction where no clinical data registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the performance period.

We seek comment on the proposed exclusions and whether there are circumstances that would require additional exclusion criteria for the measures.

In addition, we intend to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022, and are seeking public comment on whether MIPS eligible clinicians will continue to share such data with public health entities once the Public Health and Clinical Data Exchange objective is removed, as well as other policy levers outside of the Promoting Interoperability performance category that could be adopted for continued reporting to public health and clinical data registries, if necessary. As noted

above, while we believe that these registries provide the necessary monitoring of public health nationally and contribute to the overall health of the nation, we are also focusing on reducing burden and identifying other appropriate venues in which reporting to public health and clinical data registries could be reported. We are seeking public comment on the role that each of the public health and clinical data registries should have in the future of the Promoting Interoperability performance category and whether the submission of this data should still be required.

Lastly, we are seeking public comment on whether the Promoting Interoperability performance category is the best means for promoting sharing of clinical data with public health entities.

In the event we do not finalize the new scoring methodology we are proposing in section III.H.3.h.(5)(d) of this proposed rule, current Promoting Interoperability performance category objectives, measures and reporting requirements would be maintained as finalized in previous rulemaking. Therefore, all Public Health and Clinical Data Registry Reporting measures would be part of the performance and bonus score as finalized in previous rulemaking (82 FR 53674 through 53680).

To assist readers in identifying the requirements of CEHRT for the Promoting Interoperability Objectives and Measures under the scoring methodology proposed in section III.H.3.h.(5)(d) of this proposed rule, we are including Table 40, which includes the 2015 Edition certification criteria required to meet the objectives and measures.

TABLE 40—PROMOTING INTEROPERABILITY OBJECTIVES AND MEASURES AND CERTIFICATION CRITERIA FOR THE 2015 EDITION

Objective	Measure	2015 Edition
Protect Patient Health Information.	Security Risk Analysis	The requirements are a part of CEHRT specific to each certification criterion.
e-Prescribing	e-Prescribing	§ 170.315(b)(3) (Electronic Prescribing).
		§ 170.315(a)(10) (Drug-Formulary and Preferred Drug List checks).
	Query of PDMP	§ 170.315(a)(10) (Drug-Formulary and Preferred Drug List checks) and (b)(3) (Electronic Prescribing).
	Verify Opioid Treatment Agreement	§ 170.315(a)(10) (Drug-Formulary and Preferred Drug List checks) (b)(3) (Electronic Prescribing), and § 170.205(b)(2) (Electronic Prescribing Standard).
Health Information Exchange ...	Support Electronic Referral Loops by Sending Health Information.	§ 170.315(b)(1) (Transitions of Care).
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	§ 170.315(b)(1) (Transitions of Care).
		§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation).

TABLE 40—PROMOTING INTEROPERABILITY OBJECTIVES AND MEASURES AND CERTIFICATION CRITERIA FOR THE 2015 EDITION—Continued

Objective	Measure	2015 Edition
Provider to Patient Exchange ...	Provide Patients Electronic Access to Their Health Information.	§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party). § 170.315(g)(7) (Application Access—Patient Selection). § 170.315(g)(8) (Application Access—Data Category Request). § 170.315(g)(9) (Application Access—All Data Request). The three criteria combined are the “API” certification criteria.
Public Health and Clinical Data Exchange.	Immunization Registry Reporting	§ 170.315(f)(1) (Transmission to Immunization Registries).
	Syndromic Surveillance Reporting	§ 170.315(f)(2) (Transmission to Public Health Agencies—Syndromic Surveillance) Urgent Care Setting Only.
	Electronic Case Reporting	§ 170.315(f)(5) (Transmission to Public Health Agencies—Electronic Case Reporting).
	Public Health Registry Reporting	EPs may choose one or more of the following: § 170.315(f)(4) (Transmission to Cancer Registries). § 170.315(f)(7) (Transmission to Public Health Agencies—Health Care Surveys).
	Clinical Data Registry Reporting	No 2015 Edition health IT certification criteria at this time.

(vi) Request for Comment—Potential New Measures Health Information Exchange Across the Care Continuum

We are working to introduce additional flexibility to allow MIPS eligible clinicians a wider range of options in selecting measures that are most appropriate to their setting, patient population, and clinical practice improvement goals. For this reason, we are seeking comment on a potential concept for future rulemaking to add two additional measure options related to health information exchange for MIPS eligible clinicians.

The Promoting Interoperability performance category requirements for health information exchange primarily focused on the exchange between and among health care providers. While these use cases represent a significant portion of the health care industry, the care continuum is much broader and includes a wide range of health care providers and settings of care that have adopted and implemented health IT systems to support patient care and electronic information exchange. Specifically, health care providers in long-term care and post-acute care settings, skilled nursing facilities, and behavioral health settings have made significant advancements in the adoption and use of health IT. Many MIPS eligible clinicians are now engaged in bi-directional exchange of patient health information with these health care providers and settings of care and many more are seeking to incorporate these workflows as part of efforts to improve care team coordination or to support alternative payment models.

For these reasons, we are seeking comment on two potential new measures for inclusion in the program to

enable MIPS eligible clinicians to exchange health information through health IT supported care coordination across a wide range of settings.

New Measure Description for Support Electronic Referral Loops by Sending Health Information Across the Care Continuum: For at least one transition of care or referral to a provider of care other than a MIPS eligible clinician, the MIPS eligible clinician creates a summary of care record using CEHRT; and electronically exchanges the summary of care record.

New Measure Denominator: Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transitioning or referring health care provider to a provider of care other than a MIPS eligible clinician.

New Measure Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created and exchanged electronically using CEHRT.

New Measure Description for Support Electronic Referral Loops by Receiving and Incorporating Health Information Across the Care Continuum: For at least one electronic summary of care record received by a MIPS eligible clinician from a transition of care or referral from a provider of care other than a MIPS eligible clinician, the MIPS eligible clinician conducts clinical information reconciliation for medications, medication allergies, and problem list.

New Measure Denominator: The number of electronic summary of care records received for a patient encounter during the performance period for which a MIPS eligible clinician was the recipient of a transition of care or referral from a provider of care other than a MIPS eligible clinician.

New Measure Numerator: The number of electronic summary of care records received for which clinical information reconciliation was completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient’s medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy—Review of the patient’s known medication allergies; and (3) Current Problem List—Review of the patient’s current and active diagnoses.

We are seeking comment on whether these two measures should be combined into one measure so that a MIPS eligible clinician who is engaged in exchanging health information across the care continuum may include any such exchange in a single measure. We seek comment on whether the denominators should be combined to a single measure including both transitions of care to and from a MIPS eligible clinician. We further seek comment on whether the numerators should be combined to a single measure including both the sending and receiving of electronic patient health information. We are seeking comment on whether the potential new measures should be considered for inclusion in a future program year or whether stakeholders believe there is sufficient readiness and interest in the measures to implement them as early as CY 2019.

For the purposes of focusing the denominator, we are seeking comment regarding whether the potential new measures should be limited to transitions of care to and/or from referrals involving long-term and post-acute care, skilled nursing care, and behavioral health care. We also are seeking comment on whether additional settings of care should be considered for

inclusion in the denominators and whether a MIPS eligible clinician should be allowed to limit the denominators to a specific type of care setting based on their organizational needs, clinical improvement goals, or participation in an alternative payment model. We also are interested in comments regarding the feasibility of these measures in instances where a MIPS eligible clinician receives information from a non-MIPS eligible clinician that is not using CEHRT. Finally, we are seeking comment on the impact the potential new measures may have for health IT developers to develop, test, and implement a new measure calculation for a future program year.

(g) Improvement Activities Bonus Score Under the Promoting Interoperability Performance Category and Future Reporting Considerations

In the CY 2017 Quality Payment Program final rule (81 FR 77202), we discussed our approach to the measurement of the use of CEHRT to allow MIPS eligible clinicians and groups the flexibility to implement CEHRT in a way that supports their clinical needs. Toward that end, we adopted a policy for the 2017 and 2018 performance periods (81 FR 77202–77209 and 82 FR 53664–53670) and codified it at § 414.1380(b)(4)(i)(C)(2) to award a bonus score to MIPS eligible clinicians who use CEHRT to complete certain activities in the improvement activities performance category based on our belief that the use of CEHRT in carrying out these activities could further the outcomes of clinical practice improvement.

In section III.H.3.h.(5)(d) of this proposed rule, we have proposed significant changes to the scoring methodology and measures beginning with the performance period in 2019. In connection with these changes, we are not proposing to continue the bonus for completing certain improvement activities using CEHRT for the performance period in 2019 and subsequent performance periods. As discussed in section III.H.3.h.(5)(b) of this proposed rule, we are shifting the focus of this performance category to put a greater emphasis on interoperability and patient access to health information, and we do not believe awarding a bonus for performing an improvement activity using CEHRT would directly support those goals. While we continue to believe that the use of CEHRT in completing improvement activities is extremely valuable and vital to the role of CEHRT in practice improvement, we do not

believe that awarding a bonus in the Promoting Interoperability performance category would be appropriate in light of the new direction we want to take, and we seek comment on other ways to promote the use of CEHRT.

We invite comments on our decision not to propose to continue the bonus for completing certain improvement activities using CEHRT for the performance period in 2019 and subsequent performance periods.

We acknowledge that the omission of this bonus could be viewed as increasing burden, and seek to counteract that concern by evaluating other methods to reduce burden to offset this potential increase. We have also considered various ways to align and streamline the different performance categories under the MIPS. In lieu of the improvement activities bonus score, we have looked extensively at ways to link three of the performance categories—quality, improvement activities and Promoting Interoperability—to reduce burden and create a more cohesive and closely linked MIPS program. One possibility we have identified is to establish several sets of new multi-category measures that would cut across the different performance categories and allow MIPS eligible clinicians to report once for credit in all three performance categories. For example, one possible combined measure would bring together the elements of the proposed Promoting Interoperability measure, Support Electronic Referral Loops by Sending Health Information, the improvement activity, implementation of use of specialist reports back to referring clinician or group to close referral loop, and the quality measure, Closing the Referral Loop: Receipt of Specialist Report. Our goal would be to establish several of these combined measures so MIPS eligible clinicians could report once for credit across all three performance categories. At the present time, we are only seeking comment on this concept, as we are still evaluating the appropriate measure combinations and feasibility of a multi-category model. We believe that as we further develop the new focus and goals of the Promoting Interoperability performance category, we may be able to identify additional measure links that could make this concept a reality and overcome some of the challenges we currently face in implementing this concept. For example, one challenge we have identified is the lack of measures and activities that share identical and aligned requirements across the three performance categories. We seek comment on this reporting model, as well as measure and activity suggestions

to enhance the link between the three performance categories.

Furthermore, to promote measurement that provides clinicians with measures that are meaningful to their practices, we intend to consider proposing in future rulemaking MIPS public health priority sets across the four performance categories (quality, improvement activities, Promoting Interoperability, and cost). We believe that adopting such sets would provide clinicians with a cohesive reporting experience, by allowing them to focus on activities and measures that fit within their workflow, address their patient population needs, and encourage increased participation in MIPS. Furthermore, it would drive participation and continued improvement across performance categories. Consistent with the goals of the Meaningful Measures Initiative, the public health priority sets would seek to provide clinicians with sets of measures and activities that are most meaningful to them, with an emphasis on improving quality of life and outcomes for patients. The construction of public health priority sets could also identify where there are measurement gaps, and what areas measure development should focus on, such as the lack of sufficient measures for certain specialists.

The public health priority sets would be built across performance categories and decrease the burden of having to report for separate performance categories as relevant measures and activities are bundled. In developing the first few public health priority sets, we intend to focus on areas that address the opioid epidemic impacting the nation, as well as other patient wellness priorities that are attributable to more complex diseases or clinical conditions. We intend to develop the first few public health priority sets around: Opioids; blood pressure; diabetes; and general health (healthy habits). In this proposed rule, we are seeking comments on additional public health priority areas that should be considered, and whether these public health priority sets should be more specialty focused versus condition specific. We are also seeking comment on how CMS could implement public health priority sets in ways that further minimize burden for health care providers, for instance, by offering sets which emphasize use of common health IT functionalities. Finally, we are seeking comment on how CMS could encourage or incentivize health care providers to consider using these public health priority sets.

(h) Additional Considerations

(i) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

In prior rulemaking (82 FR 30079), we discussed our belief that certain types of MIPS eligible clinicians (NPs, PAs, CNSs, and CRNAs) may lack experience with the adoption and use of CEHRT. Because many of these non-physician clinicians were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we stated that we have little evidence as to whether there are sufficient measures applicable and available to these types of MIPS eligible clinicians under the advancing care information performance category. We established a policy for the performance periods in 2017 and 2018 under section 1848(q)(5)(F) of the Act to assign a weight of zero to the advancing care information performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the advancing care information performance category, but if they choose to report, they will be scored on the advancing care information performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act. We stated our intention to use data from the first performance period (2017) to further evaluate the participation of these MIPS eligible clinicians in the advancing care information performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians. As we have not yet analyzed the data for the first MIPS performance period, it would be premature to propose to alter our treatment of these MIPS eligible clinicians in year 3.

We are proposing to continue this policy for the performance period in 2019 and to codify the policy at § 414.1380(c)(2)(i)(A)(5). We request public comments on this proposal.

(ii) Physical Therapists, Occupational Therapists, Clinical Social Workers, and Clinical Psychologists

As discussed in section III.H.3.a. of this proposed rule, in accordance with section 1848(q)(1)(C)(i)(II) of the Act, we are proposing to add the following clinician types to the definition of a MIPS eligible clinician, beginning with

the performance period in 2019: Physical therapists, occupational therapists, clinical social workers, and clinical psychologists. For the reasons discussed in prior rulemaking and in the preceding section III.H.3.h.(5)(f), we are proposing to apply the same policy we adopted for NPs, PAs, CNSs, and CRNAs for the performance periods in 2017 and 2018 to these new types of MIPS eligible clinicians for the performance period in 2019. Because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category. Thus, we are proposing to rely on section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category if there are not sufficient measures applicable and available to these new types of MIPS eligible clinicians (physical therapists, occupational therapists, clinical social workers, and clinical psychologists). We encourage all of these new types of MIPS eligible clinicians to report on these measures to the extent they are applicable and available; however, we understand that some of them may choose to accept a weight of zero for this performance category if they are unable to fully report the Promoting Interoperability measures. We believe this approach is appropriate for their first performance period (in 2019) based on the payment consequences associated with reporting, the fact that many of these types of MIPS eligible clinicians may lack experience with EHR use, and our current uncertainty as to whether we have proposed sufficient measures that are applicable and available to these types of MIPS eligible clinicians. We would use their first performance period to further evaluate the participation of these MIPS eligible clinicians in the Promoting Interoperability performance category and would consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians.

These MIPS eligible clinicians may choose to submit Promoting Interoperability measures if they determine that these measures are applicable and available to them; however, if they choose to report, they would be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians and the performance category would be

given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their Promoting Interoperability performance category score.

We are proposing to codify this policy at § 414.1380(c)(2)(i)(A)(4).

(6) APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

As codified at § 414.1370, MIPS eligible clinicians, including those participating in MIPS APMs, are subject to MIPS reporting requirements and payment adjustments, unless excluded on another basis.

In the CY 2017 Quality Payment Program rule, we finalized the APM scoring standard, which is designed to reduce reporting burden for participants in certain APMs by reducing the need for duplicative data submission to MIPS and their respective APMs, and to avoid potentially conflicting incentives between those APMs and the MIPS.

We established at § 414.1370(c) that the MIPS performance period under § 414.1320 applies for the APM scoring standard. We finalized under § 414.1370(f) that, under the APM scoring standard, MIPS eligible clinicians will be scored at the APM entity group level and each MIPS eligible clinician will receive the APM Entity's final MIPS score. We propose to amend § 414.1370(f)(2) to state that if the APM Entity group is excluded from MIPS, all eligible clinicians within that APM Entity group are also excluded from MIPS.

The MIPS final score under the APM scoring standard is comprised of the four MIPS performance categories as finalized at § 414.1370(g): Quality; cost; improvement activities; and advancing care information. In 2018, these performance categories are scored at 50 percent, 0 percent, 30 percent, and 20 percent, respectively.

In this proposed rule for the APM scoring standard, we propose to: (1) Revise § 414.1370(b)(3) to clarify the requirement for MIPS APMs to assess performance on quality measures and cost/utilization, modify the Shared Savings Program quality reporting requirements by extending the reporting exception to solo practitioners; (2) remove the Promoting Interoperability (formerly advancing care information) full-TIN reporting requirement for participants in the Shared Savings Program to allow individual TIN/NPIs to report for the Promoting Interoperability performance category; and (3) update the MIPS APM measure

sets that apply for purposes of the APM scoring standard. In addition, we explain how performance feedback may be accessed by ACO participant TINs in the Shared Savings Program.

(b) MIPS APM Criteria

In the CY 2017 Quality Payment Program final rule, we established at § 414.1370(b) that for an APM to be considered a MIPS APM, it must satisfy the following criteria: (1) APM Entities participate in the APM under an agreement with CMS or by law or regulation; (2) the APM requires that APM Entities include at least one MIPS eligible clinician on a participation list; (3) the APM bases payment incentives on performance (either at the APM entity or eligible clinician level) on cost/utilization and quality measures; and (4) the APM is neither a new APM for which the first performance period begins after the first day of the MIPS performance year, nor an APM in the final year of operation for which the APM scoring standard is impracticable.

It has come to our attention that there may be some ambiguity in the third criterion at § 414.1370(b)(3). We have received questions as to whether the criterion requires MIPS APMs to base payment incentives on performance on cost/utilization “measures,” or whether it requires more generally that MIPS APMs base payment incentives on “cost/utilization.” Because we did not address this exact point in prior rulemaking and our intended policy is not strictly clear from the regulation text, we are clarifying here that we intended the word “measures” at § 414.1370(b)(3) to modify only “quality” and not “cost/utilization.” To make this criterion clearer, we are proposing to modify the regulation to specify that a MIPS APM must be designed in such a way that participating APM Entities are incented to reduce costs of care or utilization of services, or both. This proposed change to § 414.1370(b)(3) would make it clear that a MIPS APM could take into account performance in terms of cost/utilization using model design features other than the direct use of cost/utilization measures. Specifically, we are proposing to change the order in which the requirements in the third criterion are listed to state that the APM bases payment incentives on performance (either at the APM entity or eligible clinician level) on quality measures and cost/utilization.

We further would like to clarify that we will consider each distinct track of an APM and whether it meets the above criteria in order to be a MIPS APM, and that it is possible for an APM to have

tracks that are MIPS APMs and tracks that are not MIPS APMs. We would not, however, further consider whether the individual APM Entities or MIPS eligible clinicians participating within a given track each satisfy all of the above MIPS APM criteria.

For purposes of this proposal, we understand the term “track” to refer to a distinct arrangement through which an APM Entity participates in the APM, and that such participation is mutually exclusive of the APM Entity’s participation in another “track” within the same APM. For example, we would consider the two risk arrangements under OCM to be two separate “tracks.”

We also would like to clarify our interpretation of the rule at § 414.1370(b)(4)(i) for APMs that begin after the first day of the MIPS performance period for the year (currently January 1), but require participants to report quality data for quality measures tied to payment for the full MIPS performance period, beginning January 1. Under these circumstances where quality measures tied to payment must be reported for purposes of the APM from the first day of the MIPS performance period, we believe it would be counter to the purpose of the APM scoring standard to require duplicative reporting of quality measures for both the APM and MIPS, and to create potentially conflicting incentives between the quality scoring requirements and payment incentive structures under the APM and MIPS. Therefore, for the purposes of MIPS APM determinations, we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM.

Based on the MIPS APM criteria, for the 2019 MIPS performance year, we expect that ten APMs likely will satisfy the requirements to be MIPS APMs: Comprehensive ESRD Care Model (all Tracks), Comprehensive Primary Care Plus Model (all Tracks), Next Generation ACO Model, Oncology Care Model (all Tracks), Medicare Shared Savings Program (all Tracks), Medicare ACO Track 1+ Model, Bundled Payments for Care Improvement, Advanced, Independence at Home Demonstration (if extended), Maryland Total Cost of Care Model (Maryland Primary Care Program), and Vermont Medicare ACO Initiative.

(c) Calculating MIPS APM Performance Category Scores

(i) Quality Performance Category

For the quality performance category, MIPS eligible clinicians in APM Entities will continue to be scored only on the quality measures that are required under the terms of their respective APMs, and available for scoring as specified in § 414.1370(g)(1) and explained in the CY 2017 Quality Payment Program final rule (82 FR 53698, 53692).

(A) Web Interface Reporters

In the CY 2018 Quality Payment Program final, we discussed, the requirements for MIPS eligible clinicians participating in a MIPS APM that requires use of the CMS Web Interface for quality reporting, subsequently referred to as “Web Interface Reporters” (82 FR 53954). In that rule we finalized a policy to use quality measure data that participating APM Entities submit using the CMS Web Interface and CAHPS surveys as required under the terms of the APM, and to use MIPS benchmarks for these measures when APM benchmarks are not available, in order to score quality for MIPS eligible clinicians at the APM Entity level under the APM scoring standard (82 FR 53568, 53692). We also codified at § 414.1370(f)(1) a policy under which, in the event a Shared Savings Program ACO does not report quality measures as required by the Shared Savings Program under § 425.508, each ACO participant TIN will be treated as a unique APM entity for purposes of the APM scoring standard, and may report data for the MIPS quality performance category according to the MIPS submission and reporting requirements.

For the 2019 MIPS performance year, we anticipate that there will be four Web Interface Reporter APMs: The Shared Savings Program; the Track 1+ Model; Next Generation ACO Model; and the Vermont ACO Medicare Initiative.

(aa) Complete Reporting Requirement

Under § 414.1370(f)(1), if a Shared Savings Program ACO does not report data on quality measures as required by the Shared Savings Program under § 425.508, each ACO participant TIN will be treated as a unique APM Entity for purposes of the APM scoring standard and the ACO participant TINs may report data for the MIPS quality performance category according to the MIPS submission and reporting requirements. We would like to clarify that any “partial” reporting through the CMS Web Interface that does not satisfy

the requirements of the Shared Savings Program will be considered a failure to report. Should a Shared Savings Program ACO fail to report, the exception under § 414.1370(f)(1) is triggered. In this scenario, each ACO participant TIN has the opportunity to report quality data to MIPS according to MIPS group reporting requirements in order to avoid a score of zero for the quality performance category (81 FR 77256).

We recognize that, under this policy, successfully reporting to MIPS according to group reporting requirements may be difficult for solo practitioners, for whom case thresholds and other requirements may make many group reporting measures unavailable. Therefore, we are modifying the exception such that beginning in 2019, in the case of a Shared Savings Program ACO's failure to report quality measures as required by the Shared Savings Program we would also allow a solo practitioner (a MIPS eligible clinician who has only one NPI billing through their TIN), to report on any available MIPS measures, including individual measures, in the event that their ACO fails to complete reporting for all Web Interface measures.

We are also proposing that, beginning with the 2019 performance period, the complete reporting requirement for Web Interface reporters be modified to specify that if an APM Entity (in this case, an ACO) fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey, we will score the CAHPS for ACOs survey and apply it towards the APM Entity's quality performance category score. In this scenario the Shared Savings Program TIN-level reporting exception would not be triggered and all MIPS eligible clinicians within the ACO would receive the APM Entity score.

We seek comment on this proposal.

(B) Other MIPS APMs

Under § 414.1370(g)(1)(ii), the MIPS quality performance category score for a MIPS performance period is calculated for the APM Entity using the data submitted by the APM Entity based on measures specified by us through notice and comment rulemaking and available for scoring for each Other MIPS APM from among those used under the terms of the Other MIPS APM.

In the 2019 MIPS performance year, we anticipate that there will be up to six Other MIPS APMs for which we will use this scoring methodology, based on their respective measure sets and reporting requirements: The Oncology Care Model; Comprehensive ESRD Care Model; Comprehensive Primary Care Plus Model; the Bundled Payments for Care Improvement Advanced; Maryland Primary Care Program; and Independence at Home Demonstration (in the event of an extension).

(ii) Promoting Interoperability Performance Category

In the CY 2017 Quality Payment Program final rule (81 FR 77262 through 77264; 81 FR 77266 through 77269), we established a policy at § 414.1370(g)(4)(ii) for MIPS APMs other than the Shared Savings Program, under which we attribute one Promoting Interoperability performance category score to each MIPS eligible clinician in an APM Entity group based on either individual or group-level data submitted for the MIPS eligible clinician and using the highest available score. We will then use these scores to create an APM Entity group score equal to the average of the highest scores available for each MIPS eligible clinician in the APM Entity group.

For the Shared Savings Program, we also finalized at § 414.1370(g)(4)(i) that ACO participant TINs are required to report on the Promoting Interoperability performance category, and we will weight and aggregate the ACO participant TIN scores to determine an

APM Entity group score (81 FR 77258 through 77260). This policy was meant to align requirements between the MIPS Promoting Interoperability measures and the Shared Savings Program ACO-11 measure, which is used to assess Shared Savings Program ACOs based on the MIPS Promoting Interoperability measures. However, we have found that limiting reporting to the ACO participant TIN creates unnecessary confusion, and restricts Promoting Interoperability reporting options for MIPS eligible clinicians who participate in the Shared Savings Program. Therefore, beginning in the 2019 MIPS performance period, we are proposing to no longer apply the requirement as finalized at § 414.1370(g)(4)(i) and instead to apply the existing policy at § 414.1370(g)(4)(ii) to MIPS eligible clinicians who participate in the Shared Savings Program so that they may report on the Promoting Interoperability performance category at either the individual or group level like all other MIPS eligible clinicians under the APM scoring standard.

We seek comment on this proposal.

(d) MIPS APM Performance Feedback

As we discussed in the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77270, and 82 FR 53704 through 53705, respectively), MIPS eligible clinicians who are scored under the APM scoring standard will receive performance feedback under section 1848(q)(12) of the Act.

Regarding access to performance feedback, we should note that whereas split-TIN APM Entities and their participants can only access their performance feedback at the APM Entity or individual MIPS eligible clinician level, MIPS eligible clinicians participating in the Shared Savings Program, which only includes full-TIN ACOs, will be able to access their performance feedback at the ACO participant TIN level.

(e) Measure Sets

TABLE 41—MIPS APM MEASURE LIST—COMPREHENSIVE ESRD CARE

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
Diabetes Care: Eye Exam.	0055	Effective Clinical Care	Percentage of patients 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	NCQA.

TABLE 41—MIPS APM MEASURE LIST—COMPREHENSIVE ESRD CARE—Continued

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
Diabetes Care: Foot Exam.	0056	Effective Clinical Care	Percentage of patients 18–75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the previous measurement year.	NCQA.
Advance Care Plan	0326	Communication and Care Coordination.	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	NCQA.
Medication Reconciliation Post-Discharge.	0554	Communication and Care Coordination.	The percentage of discharges from any inpatient facility (e.g., hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following the discharge in the office by the physicians, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. National Committee for Quality Assurance. This measure is reported as three rates stratified by age group: <ul style="list-style-type: none"> • Reporting Criteria 1: 18–64 years of age. • Reporting Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and Older. 	NCQA.
Influenza Immunization for the ESRD Population.	Not Endorsed	N/A	Percentage of patients aged 6 months and older seen for a visit between July 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	KCQA.
Pneumococcal Vaccination Status.	0043	Community/Population Health.	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	NCQA.
Screening for Clinical Depression and Follow-Up Plan.	0418	Community/Population Health.	Percentage of patients aged 12 and older screened for depression on the date of the encounter and using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	CMS.
Tobacco Use: Screening and Cessation Intervention.	0028	Community/Population Health.	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	PCPI Foundation.
Falls: Screening, Risk Assessment, and Plan of Care to Prevent Future Falls.	0101	Patient Safety	(A) Screening for Future Fall Risk: Patients who were screened for future fall risk at last once within 12 months. (B) Multifactorial Falls Risk Assessment: Patients at risk of future fall who had a multifactorial risk assessment for falls completed within 12 months. (C) Plan of Care to Prevent Future Falls: Patients at risk of future fall with a plan of care or falls prevention documented within 12 months.	NCQA.
ICH CAHPS: Nephrologists' Communication and Caring.	0258	N/A	Summary/Survey Measures may include: <ul style="list-style-type: none"> • Getting timely care, appointments, and information. • How well providers communicate. • Patients' rating of provider. • Access to specialists. • Health promotion and education. • Shared Decision-making. 	CMS.

TABLE 41—MIPS APM MEASURE LIST—COMPREHENSIVE ESRD CARE—Continued

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
ICH CAHPS: Quality of Dialysis Center Care and Operations.	0258	N/A	<ul style="list-style-type: none"> • Health status and functional status. • Courteous and helpful office staff. • Care coordination. • Between visit communication. • Helping you to take medications as directed, and • Stewardship of patient resources. <p>Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.</p>	CMS.
ICH CAHPS: Providing Information to Patients.	0258	N/A	<p>Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.</p>	CMS.
ICH CAHPS: Rating of the Nephrologist.	0258	N/A	<p>Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.</p>	CMS.
ICH CAHPS: Rating of Dialysis Center Staff.	0258	N/A	<p>Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.</p>	CMS.
ICH CAHPS: Rating of the Dialysis Facility.	0258	N/A	<p>Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.</p>	CMS.
Standardized Mortality Ratio.	0369	N/A	<p>This measure is calculated as a ratio but expressed as a rate.</p>	CMS.
Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR).	Not Endorsed	N/A	<p>The standardized ratio of the observed to expected number of incident patients under age 75 listed on the kidney or kidney-pancreas transplant waitlist or who received a living donor transplant within the first year of initiating dialysis based on the national rate.</p>	CMS.
Percentage of Prevalent Patients Waitlisted (PPPW).	Not Endorsed	N/A	<p>The percentage of patients who were on the kidney or kidney-pancreas transplant waitlist.</p>	CMS.

TABLE 42—MIPS APM MEASURE LIST—COMPREHENSIVE PRIMARY CARE PLUS (CPC+) MODEL

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measures steward
Controlling High Blood Pressure.	0018	Effective Treatment/ Clinical Care.	Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance.
Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%).	0059	Effective Treatment/ Clinical Care.	Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c >9.0% during the measurement period.	National Committee for Quality Assurance.
Dementia: Cognitive Assessment.	2872	Effective Treatment/ Clinical Care.	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	PCPI Foundation.
Falls: Screening for Future Fall Risk.	0101	Patient Safety	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance.
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment.	0004	Effective Treatment/ Clinical Care.	Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance.
Closing the Referral Loop: Receipt of Specialist Report.	Not Endorsed	Communication and Care Coordination.	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	CMS.
Cervical Cancer Screening.	0032	Effective Treatment/ Clinical Care.	Percentage of women 21–64 years of age, who were screened for cervical cancer using either of the following criteria. • Women age 21–64 who had cervical cytology performed every 3 years. • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance.
Colorectal Cancer Screening.	0034	Effective Treatment/ Clinical Care.	Percentage of patients, 50–75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance.
Diabetes: Eye Exam	0055	Effective Treatment/ Clinical Care.	Percentage of patients 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance.
Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.	0028	Community/Population Health.	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months and who received cessation counseling intervention if identified as a tobacco user.	PCPI Foundation.
Breast Cancer Screening.	2372	Effective Treatment/ Clinical Care.	Percentage of women 50–74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance.
CG—CAHPS Survey 3.0—modified for CPC+.	Not Endorsed	Person and Caregiver- Centered Experience and Outcomes.	CG—CAHPS Survey 3.0	AHRQ.
Inpatient Hospital Utilization.	Not Endorsed	Communication and Care Coordination.	For members 18 years of age and older, the risk-adjusted ratio of observed to expected acute inpatient discharges during the measurement year reported by Surgery, Medicine, and Total.	National Committee for Quality Assurance.
Emergency Department Utilization.	Not Endorsed	Communication and Care Coordination.	For members 18 years of age and older, the risk-adjusted ratio of observed to expected emergency department (ED) visits during the measurement year.	National Committee for Quality Assurance.

TABLE 42—MIPS APM MEASURE LIST—COMPREHENSIVE PRIMARY CARE PLUS (CPC+) MODEL—Continued

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measures steward
Diabetes: Medical Attention for Nephropathy.	0062	Effective Treatment/ Clinical Care.	The percentage of patients 18–75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance.
Preventive Care and Screening: Depression and Follow-Up Plan.	0418	Community/Population Health.	Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	PCPI Foundation.
Depression Utilization of the PHQ–9 Tool.	0712	Effective Treatment/ Clinical Care.	The percentage of patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ–9 during each applicable 4 month period in which there was a qualifying visit.	MN Community Measurement.
Preventive Care and Screening: Influenza Immunization.	0041	Community/Population Health.	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	American Medical Association-convened Physician Consortium for Performance Improvement(R) (AMA–PCPI).
Pneumococcal Vaccination Status for Older Adults.	Not Endorsed	Community/Population Health.	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance.
Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet.	0068	Effective Treatment/ Clinical Care.	Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance.
Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.	Not Endorsed	Effective Treatment/ Clinical Care.	Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: <ul style="list-style-type: none"> • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥ 21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL–C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40–75 years with a diagnosis of diabetes with a fasting or direct LDL–C level of 70–189 mg/dL. 	CMS.
Use of High-Risk Medications in the Elderly.	0022	Patient Safety	Percentage of patients 65 years of age and older who were ordered high-risk medications.	National Committee for Quality Assurance.
Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.	Not Endorsed	Community/Population Health.	Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	CMS.
Documentation of Current Medications in the Medical Record.	0419	Patient Safety	Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	CMS.

TABLE 42—MIPS APM MEASURE LIST—COMPREHENSIVE PRIMARY CARE PLUS (CPC+) MODEL—Continued

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measures steward
Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan.	0421	Community/Population Health.	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter.	CMS.
Diabetes: Foot Exam	0056	Effective Treatment/ Clinical Care.	Percentage of patients 18–75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the previous measurement year.	National Committee for Quality Assurance.
Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).	0081	Effective Treatment/ Clinical Care.	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.	PCPI Foundation.
Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).	0083	Effective Treatment/ Clinical Care.	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.	PCPI Foundation.
Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%).	0070	Effective Treatment/ Clinical Care.	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have a prior MI or a current or prior LVEF <40% who were prescribed beta-blocker therapy.	PCPI Foundation.
Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture.	Not Endorsed	Effective Treatment/ Clinical Care.	Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	CMS.
HIV Screening	Not Endorsed	Community/Population Health.	Percentage of patients 15–65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention (CDC).
Total Resource Use Population-based PMPM Index (RUI).	1598	N/A	This measure is used to assess the total resource use index population-based per member per month (PMPM). The Resource Use Index (RUI) is a risk adjusted measure of the frequency and intensity of services utilized to manage a provider group's patients. Resource use includes all resources associated with treating members including professional, facility inpatient and outpatient, pharmacy, lab, radiology, ancillary and behavioral health services.	Minneapolis (MN): Health Partners.

TABLE 43—MIPS APM MEASURE LIST—ONCOLOGY CARE MODEL

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
Adjuvant chemotherapy is recommended or administered within 4 months (120 days) of diagnosis to patients under the age of 80 with AJCC III (lymph node positive) colon cancer.	0223	Communication and Care Coordination.	Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is recommended and not received or administered within 4 months (120 days) of diagnosis.	Commission on Cancer, American College of Surgeons.
Breast Cancer: Hormonal Therapy for Stage I (T1b)–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer.	0387	Communication and Care Coordination.	Percentage of female patients aged 18 years and older with Stage I (T1b) through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.	AMA-convened Physician Consortium for Performance Improvement.
Oncology: Medical and Radiation—Plan of Care for Pain.	0384	Person and Caregiver-Centered Experience and Outcomes.	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology.
Combination chemotherapy is recommended or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cN0M0, or Stage IB–III hormone receptor negative breast cancer.	0559	Communication and Care Coordination.	Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0 (tumor greater than 1 cm), or Stage IB–III, whose primary tumor is progesterone and estrogen receptor negative recommended for multiagent chemotherapy (recommended or administered) within 4 months (120 days) of diagnosis.	Commission on Cancer, American College of Surgeons.
Documentation of Current Medications in the Medical Record.	0419	Patient Safety	Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over the counters, herbals, and vitamin/mineral/dietary AND must contain the medications' name, dosage, frequency and route of administration.	CMS.
Oncology: Medical and Radiation—Pain Intensity Quantified.	0383	Person and Caregiver-Centered Experience.	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Physician Consortium for Performance Improvement Foundation.
Patient-Reported Experience of Care.	N/A	Person and Caregiver-Centered Experience and Outcomes.	Summary/Survey Measures may include: <ul style="list-style-type: none"> • Overall measure of patient experience. • Exchanging Information with Patients. • Access. • Shared Decision Making. • Enabling Self-Management. • Affective Communication. 	CMS.
Preventive Care and Screening: Screening for Depression and Follow-Up Plan.	0418	Community/Population Health.	Percentage of patients aged 12 and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool and if positive, a follow-up plan is documented on the date of the positive screen.	CMS.
Proportion of patients who died who were admitted to hospice for 3 days or more.	N/A	N/A	Percentage of OCM-attributed FFS beneficiaries who died and spent at least 3 days in hospice during the measurement time period.	CMS.
Risk-adjusted proportion of patients with all-cause ED visits that did not result in a hospital admission within the 6-month episode.	N/A	N/A	Percentage of OCM-attributed FFS beneficiaries who had an ER visit that did not result in a hospital stay during the measurement period.	CMS.

TABLE 43—MIPS APM MEASURE LIST—ONCOLOGY CARE MODEL—Continued

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
Risk-adjusted proportion of patients with all-cause hospital admissions within the 6-month episode.	N/A	N/A	Percentage of OCM-attributed FFS beneficiaries who were had an acute-care hospital stay during the measurement period.	CMS.
Trastuzumab administered to patients with AJCC stage I (T1c)–III and human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy.	1858	Efficiency and Cost reduction.	Proportion of female patients (aged 18 years and older) with AJCC stage I (T1c)–III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant Chemotherapy.	American Society of Clinical Oncology.

TABLE 44—MIPS APM MEASURE LIST—BUNDLED PAYMENTS FOR CARE IMPROVEMENT ADVANCED

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
All-Cause Hospital Re-admission.	1789	Communication and Care Coordination.	This measure estimates a hospital-level risk-standardized readmission rate (RSRR) of unplanned, all cause readmission after admission for any eligible condition within 30 days of hospital discharge.	CMS.
Advanced Care Plan	0326	Communication and Care Coordination.	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	NCQA.
Perioperative Care: Selection of Prophylactic Antibiotic: First or Second Generation Cephalosporin.	0268	Patient Safety	Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic who had an order for first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons.
Hospital-Level Risk-Standardized Mortality Rate Following Elective Coronary Artery Bypass Graft Surgery.	2558	Patient Safety	The measure estimates a hospital-level, risk-standardized mortality rate (RSMR) for patients 18 years and older discharged from the hospital following a qualifying isolated CABG procedure. Mortality is defined as death from any cause within 30 days of the procedure date of an index CABG admission. The measure was developed using Medicare Fee-for-Service (FFS) patients 65 years and older and was tested in all-payer patients 18 years and older. An index admission is the hospitalization for a qualifying isolated CABG procedure considered for the mortality outcome.	CMS.

TABLE 44—MIPS APM MEASURE LIST—BUNDLED PAYMENTS FOR CARE IMPROVEMENT ADVANCED—Continued

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
Excess Days in Acute Care After Hospitalization for Acute Myocardial Infarction.	2881	Patient Safety	This measure assesses days spent in acute care within 30 days of discharge from an inpatient hospitalization for acute myocardial infarction (AMI) to provide a patient-centered assessment of the post-discharge period. This measure is intended to capture the quality of care transitions provided to discharged patients hospitalized with AMI by collectively measuring a set of adverse acute care outcomes that can occur post-discharge: Emergency department (ED) visits, observation stays, and unplanned readmissions at any time during the 30 days post-discharge. In order to aggregate all three events, we measure each in terms of days. In 2016, CMS will begin annual reporting of the measure for patients who are 65 years or older, are enrolled in fee-for-service (FFS) Medicare, and are hospitalized in non-federal hospitals.	CMS.
AHRQ Patient Safety Measures.	0531	Patient Safety	The modified PSI-90 Composite measure (name changed to Patient Safety and Adverse Events Composite) consists of ten component indicators: PSI-3 Pressure ulcer rate; PSI-6 Iatrogenic pneumothorax rate; PSI-8 Postoperative hip fracture rate; PSI-09 Perioperative hemorrhage or hematoma rate; PSI-10 physiologic and metabolic derangement rate; PSI-11 postoperative respiratory failure rate; PSI-12 Perioperative pulmonary embolism or Deep vein thrombosis rate; PSI-13 Postoperative sepsis rate; PSI-14 Postoperative wound dehiscence rate; and PSI-15 Accidental puncture or laceration rate.	AHRQ.
Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty.	1550	Patient Safety	The measure estimates a hospital-level risk-standardized complication rate (RSCR) associated with elective primary THA and TKA in Medicare Fee-For-Service beneficiaries who are 65 years and older. The outcome (complication) is defined as any one of the specified complications occurring from the date of index admission to 90 days post date of the index admission (the admission included in the measure cohort).	CMS.

TABLE 45—MIPS APM MEASURE LIST—MARYLAND TOTAL COST OF CARE MODEL
[Maryland Primary Care Program]

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
Controlling High Blood Pressure.	0018	Effective Treatment/ Clinical Care.	Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance.
Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%).	0059	Effective Treatment/ Clinical Care.	Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c >9.0% during the measurement period.	National Committee for Quality Assurance.
Dementia: Cognitive Assessment.	2872	Effective Treatment/ Clinical Care.	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Medical Association-convened Physician Consortium for Performance Improvement (AMA-PCPI).

TABLE 45—MIPS APM MEASURE LIST—MARYLAND TOTAL COST OF CARE MODEL—Continued
[Maryland Primary Care Program]

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
Falls: Screening for Future Fall Risk.	0101	Patient Safety/Safety ..	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance.
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment.	004	Effective Treatment/Clinical Care.	Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance.
Closing the Referral Loop: Receipt of Specialist Report.	N/A	Communication and Coordination/Care Coordination.	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	CMS.
Cervical Cancer Screening.	0032	Effective Treatment/Clinical Care.	Percentage of women 21–64 years of age, who were screened for cervical cancer using either of the following criteria. • Women age 21–64 who had cervical cytology performed every 3 years. • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every.	National Committee for Quality Assurance.
Colorectal Cancer Screening.	0034	Effective Treatment/Clinical Care.	Percentage of patients, 50–75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance.
Diabetes: Eye Exam	0055	Effective Treatment/Clinical Care.	Percentage of patients 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance.
Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.	0028	Healthy Living/Population Health and Prevention.	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months and who received cessation counseling intervention if identified as a tobacco user.	American Medical Association-convened Physician Consortium for Performance Improvement(R) (AMA–PCPI).
Breast Cancer Screening.	2372	Effective Treatment/Clinical Care.	Percentage of women 50–74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance.
CG–CAHPS Survey 3.0—modified for CPC+.	Not Endorsed	Person and Family Engagement/Patient and Caregiver Experience.	CG–CAHPS Survey 3.0	AHRQ.
Inpatient Hospital Utilization.	Not Endorsed	Communication and Care Coordination.	For members 18 years of age and older, the risk-adjusted ratio of observed to expected acute inpatient discharges during the measurement year reported by Surgery, Medicine, and Total.	National Committee for Quality Assurance.
Emergency Department Utilization.	Not Endorsed	Communication and Care Coordination.	For members 18 years of age and older, the risk-adjusted ratio of observed to expected emergency department (ED) visits during the measurement year.	National Committee for Quality Assurance.
Diabetes: Medical Attention for Nephropathy.	0062	Effective Treatment/Clinical Care.	The percentage of patients 18–75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance.
Preventive Care and Screening: Depression and Follow-Up Plan.	0418	Community/Population Health.	Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	CMS.

TABLE 45—MIPS APM MEASURE LIST—MARYLAND TOTAL COST OF CARE MODEL—Continued
[Maryland Primary Care Program]

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
Depression Utilization of the PHQ-9 Tool.	0712	Effective Treatment/Clinical Care.	The percentage of patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying visit.	MN Community Measurement.
Preventive Care and Screening: Influenza Immunization.	0041	Healthy Living/Population Health and Prevention.	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	American Medical Association-convened Physician Consortium for Performance Improvement(R) (AMA-PCPI).
Pneumococcal Vaccination Status for Older Adults.	0043	Healthy Living/Population Health and Prevention.	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance.
Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet.	0068	Effective Treatment/Clinical Care.	Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance.
Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.	Not Endorsed	Effective Treatment/Clinical Care.	Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: <ul style="list-style-type: none"> Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR Adults aged ≥ 21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR Adults aged 40–75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70–189 mg/dL. 	CMS.
Use of High-Risk Medications in the Elderly.	0022	Patient Safety/Safety ..	Percentage of patients 65 years of age and older who were ordered high-risk medications.	National Committee for Quality Assurance.

TABLE 46—MIPS APM MEASURE LIST—INDEPENDENCE AT HOME DEMONSTRATION

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
Number of inpatient admissions for ambulatory-care sensitive conditions per 100 patient enrollment months.	Not Endorsed	N/A	Number of inpatient admissions for ambulatory-care sensitive conditions per 100 patient enrollment months.	CMS.
Number of readmissions within 30 days per 100 inpatient discharges.	Not Endorsed	N/A	Risk adjusted readmissions to a hospital within 30 days following discharge from the hospital for an index admission.	CMS.
Emergency Department Visits for Ambulatory Care Sensitive Conditions.	Not Endorsed	N/A	Risk adjusted emergency department visits for three ambulatory care sensitive conditions: diabetes, congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD).	CMS.

TABLE 46—MIPS APM MEASURE LIST—INDEPENDENCE AT HOME DEMONSTRATION—Continued

Measure name	NQF/Quality ID No.	National quality strategy domain	Measure description	Primary measure steward
Contact with beneficiaries within 48 hours upon admission to the hospital and discharge from the hospital and/or ED.	Not Endorsed	N/A	Percent of hospital admissions, hospital discharges, and emergency department (ED) visits for beneficiaries enrolled in IAH with a follow-up contact within 48 hours.	CMS.
Medication reconciliation in the home.	Not Endorsed	N/A	Percent of hospital discharges and emergency department (ED) visits for beneficiaries enrolled in IAH with medication reconciliation in the home within 48 hours.	CMS.
Percentage with Documented Patient Preferences.	Not Endorsed	N/A	Percent of beneficiaries enrolled in IAH with patient preferences documented in the medical record for a demonstration year.	CMS.

i. MIPS Final Score Methodology

(1) Converting Measures and Activities Into Performance Category Scores

(a) Background

For the 2021 MIPS payment year, we intend to build on the scoring methodology we finalized for the transition years, which allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. The rationale for our scoring methodology continues to be grounded in the understanding that the MIPS scoring system has many components and various moving parts.

As we continue to move forward in implementing the MIPS program, we strive to balance the statutory requirements and programmatic goals with the ease of use, stability, and meaningfulness for MIPS eligible clinicians. We do so while also emphasizing simplicity and the continued development of a scoring methodology that is understandable for MIPS eligible clinicians.

In the CY 2017 Quality Payment Program final rule, we finalized a unified scoring system to determine a final score across the 4 performance categories (81 FR 77273 through 77276). For the 2019 MIPS performance period, we propose to build on the scoring methodology we previously finalized, focusing on encouraging MIPS eligible clinicians to meet data completeness requirements. For the quality performance category scoring, we propose to extend some of the transition year policies to the 2019 MIPS performance period, and we are also proposing several modifications to existing policies. In the CY 2018 Quality Payment Program final rule (82 FR 53712 through 53714), we established a methodology for scoring improvement in the cost performance category. However, as required by section

51003(a)(1)(B) of the Bipartisan Budget Act of 2018, we propose that the cost performance category score would not take into account improvement until the 2024 MIPS payment year. In the CY 2018 Quality Payment Program final rule (82 FR 53753 through 53767), we finalized the availability of a facility-based measurement option for clinicians who met certain requirements, beginning with the 2019 MIPS performance period; in section III.H.3.i.(1)(d) of this proposed rule, we propose to change the determination of facility-based measurement to include consideration of presence in the on-campus outpatient hospital. The policies for scoring the 4 performance categories are described in detail in section III.H.3.i.(1) of this proposed rule.

These sets of proposed policies will help eligible clinicians as they participate in the 2019 MIPS performance period/2021 MIPS payment year, and as we move beyond the transition years of the program. Section 51003 of the Bipartisan Budget Act of 2018 provides flexibility to continue the gradual ramp up of the Quality Payment Program and enables us to extend some of the transition year policies to the 2019 performance period.

Unless otherwise noted, for purposes of this section III.H.3.i. of this proposed rule on scoring, the term “MIPS eligible clinician” will refer to MIPS eligible clinicians who collect and submit data and are scored at either the individual or group level, including virtual groups; it will not refer to MIPS eligible clinicians who are scored by facility-based measurement, as discussed in section III.H.3.i.(1)(d) of this proposed rule. We also note that the APM scoring standard applies to MIPS eligible clinicians in APM Entities in MIPS APMs, and those policies take precedence where applicable. Where those policies do not apply, scoring for MIPS eligible clinicians as described in

section III.H.3.h.(6) of this proposed rule will apply. We refer readers to section III.H.4. of this proposed rule for additional information about the APM scoring standard.

(b) Scoring the Quality Performance Category for the Following Collection Types: Part B Claims Measures, eQCMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

Although we do not propose changing the basic scoring system that we finalized in the CY 2018 Quality Payment Program final rule for the 2021 MIPS payment year (82 FR 53712 through 53748), we are proposing several modifications to scoring the quality performance category, including removing high-priority measure bonus points for CMS Web Interface measures and extending the bonus point caps, and adding a small practice bonus to the quality performance category score. The following section describes these previously finalized policies and our new proposals.

We are also proposing updates to § 414.1380(b)(1) in an effort to more clearly and concisely capture previously established policies. These proposed updates are not intended to be substantive in nature, but rather to bring more clarity to the regulatory text. We will make note of the updated regulatory citations in their relevant sections below.

(i) Scoring Terminology

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 through 77831, and 82 FR 53568 through 54229, respectively), we used the term “submission mechanisms” in reference to the various ways in which a MIPS eligible clinician or group can submit data to CMS. As discussed in section III.H.3.h.(1)(b) of this proposed

rule, it has come to our attention that the way we have described the various ways in which MIPS eligible clinicians, groups and third-party intermediaries can submit data to our systems does not accurately reflect the experience users have when submitting data to us. We refer readers to section III.H.3.h.(1)(b) of this proposed rule for further discussion on our proposed changes to the scoring terminology related to measure specification and data collection and submission. For additional discussion on the impact of the proposed terminology change on our benchmarking methodology, validation process, and end-to-end reporting bonus, we refer readers to sections III.H.3.i.(1)(b)(ii), (v), and (x) of this proposed rule.

(ii) Quality Measure Benchmarks

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77282, and 82 FR 53718, respectively) for our previously established benchmarking policies. As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.H.3.i.(1)(a)(i) of this proposed rule, our previously established benchmarking policies at § 414.1380(b)(1)(i) through (iii) would now be referenced at § 414.1380(b)(1)(i) through (ii).

In the CY 2018 Quality Payment Program final rule, we solicited comments on how we could improve our method of benchmarking quality measures (82 FR 53718 through 53719). Several commenters provided suggestions on improving our benchmarking methodology including reconciling the differences between the MIPS and Physician Compare benchmarking methodologies. Several other commenters expressed concerns that the methodology may not reflect performance because, among other reasons, commenters believed that the benchmarks use data from a small number of clinicians, are based on various legacy programs, and create ranging point variances based on collection type.

When we developed the quality measure benchmarks, we sought to develop a system that enables MIPS eligible clinicians, beneficiaries, and other stakeholders to understand what is required for a strong performance in MIPS while being consistent with statutory requirements (81 FR 28249 through 28250). The feedback we have received thus far from stakeholders on our benchmarks is helping to inform our approach to the benchmarking methodology, especially as we look for possible ways of aligning with

Physician Compare benchmarks. As described in section III.H.3.i.(1)(b)(xii) of this proposed rule, we are seeking comment on potential future approaches to scoring the quality performance category to continue to promote value and improved outcomes. We anticipate changes in scoring would be paired with potential modifications to measure selection and criteria discussed in section III.H.3.h.(2)(b) of this proposed rule. We are looking for opportunities to further reduce confusion about our benchmarking methodology described in the CY 2017 Quality Payment Program final rule (81 FR 77277 through 77278), which includes further clarification of our benchmarking process and potential areas of alignment between the MIPS and Physician Compare benchmarking methodologies. We will take commenters' suggestions into consideration in future rulemaking.

(A) Revised Terminology for MIPS Benchmarks

We previously established at § 414.1380(b)(1)(iii) separate benchmarks for the following submission mechanisms: EHR; QCDR/registry, claims; CMS Web Interface; CMS-approved survey vendor; and administrative claims. We are not proposing to change our basic approach to our benchmarking methodology; however, we are proposing to amend § 414.1380(b)(1)(ii) consistent with the proposed data submission terminology changes discussed in section III.H.3.h.(1)(b) of this proposed rule. Specifically, beginning with the 2021 MIPS payment year, we propose to establish separate benchmarks for the following collection types: eQCMs; QCDR measures (as described at § 414.1400(e)); MIPS CQMs; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. We would apply benchmarks based on collection type rather than submission mechanism. For example, for an eQCM, we would apply the eQCM benchmark regardless of submitter type (MIPS eligible clinician, group, third party intermediary). In addition, we would establish separate benchmarks for QCDR measures and MIPS CQMs since these measures do not have comparable specifications. In addition, we note that our proposed benchmarking policy allows for the addition of future collection types as the universe of measures continues to evolve and as new technology is introduced. Specifically, we propose to amend § 414.1380(b)(1)(ii) to remove the mention of each individual benchmark and instead state that benchmarks will

be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

(iii) Assigning Points Based on Achievement

In the CY 2017 Quality Payment Program final rule, we established the policies for scoring quality measures performance (81 FR 77286). We refer readers to § 414.1380(b)(1) for more on these policies.

(A) Floor for Scored Quality Measures

For the 2019 and 2020 MIPS payment years, we finalized at § 414.1380(b)(1)(i) a global 3-point floor for each scored quality measure, as well as for the hospital readmission measure (if applicable). In this way, MIPS eligible clinicians would receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements (81 FR 77286 through 77287; 82 FR 53719). For measures with a benchmark based on the performance period (rather than on the baseline period), we stated that we would continue to assign between 3 and 10 measure achievement points for performance periods after the first transition year (81 FR 77282, 77287; 82 FR 53719). For measures with benchmarks based on the baseline period, we stated that the 3-point floor was for the transition year and that we would revisit the 3-point floor in future years (81 FR 77286 through 77287; 82 FR 53719).

For the 2021 MIPS payment year, we propose to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period, and to amend § 414.1380(b)(1)(i) accordingly. We will revisit the 3-point floor for such measures again in future rulemaking.

(B) Additional Policies for the CAHPS for MIPS Measure Score

While participating in the CAHPS for MIPS survey is optional for all groups, some groups will be unable to participate in the CAHPS for MIPS survey because they do not meet the minimum beneficiary sampling requirements. CMS has sampling requirements for groups of 100 or more eligible clinicians, 25 to 99 eligible clinicians, and 2 to 24 eligible clinicians to ensure an adequate number of survey responses and the ability to reliably report data. Our sampling timeframes (82 FR 53630 through 53632) necessitate notifying groups of their inability to

meet the sampling requirements late in the performance period (see 82 FR 53630 through 53632). As a result, we are concerned that some groups that expect and plan to meet the quality performance category requirements using the CAHPS for MIPS survey may find out late in the performance period that they are unable to meet the sampling requirements and, therefore, are unable to have their performance assessed on this measure. These groups may need to report on another measure to meet the requirements of the quality performance category.

We want to encourage the reporting of the CAHPS for MIPS survey and do not want the uncertainty regarding sampling requirements to be a barrier to selecting the CAHPS for MIPS survey. To mitigate this concern, beginning with the 2021 MIPS payment year, we are proposing to reduce the denominator (that is, the total available measure achievement points) for the quality performance category by 10 points for groups that register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements. By reducing the denominator instead of only assigning the group a score of zero measure achievement points (because the group would be unable to submit any CAHPS for MIPS survey data), we are effectively removing the impact of the group's inability to submit the CAHPS for MIPS survey. We believe this reduction in denominator would remove any need for groups to find another measure if they are unable to submit the CAHPS for MIPS survey. Therefore, we propose to amend § 414.1380 to add paragraph (b)(1)(vii)(B) to state that we will reduce the total available measure achievement points for the quality performance category by 10 points for groups that registered for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements.

We do not want groups to register for the CAHPS for MIPS survey if they know in advance that they are unlikely to be able to meet the sampling requirement, so we seek comment on whether we should limit this proposed policy to groups for only one MIPS performance period. For example, for the performance period following the application of this proposed policy, a

notice could be provided to groups during registration indicating that if the sampling requirement is not met for a second consecutive performance period, the proposed policy will not be applied. This would provide notice to the group that they may not meet the sampling requirement needed for the CAHPS for MIPS survey and may need to look for alternate measures, but does not preclude the group from registering for the CAHPS for MIPS survey if they expect to meet the minimum beneficiary sampling requirements in the second MIPS performance period.

(iv) Assigning Measure Achievement Points for Topped Out Measures

We refer readers to CY 2017 Quality Payment Program final rule (82 FR 53721 through 53727) for our established policies for scoring topped out measures.

Under § 414.1380(b)(1)(xiii)(A), for the 2020 MIPS payment year, six measures will receive a maximum of 7 measure achievement points, provided that the applicable measure benchmarks are identified as topped out again in the benchmarks published for the 2018 MIPS performance period. Under § 414.1380(b)(1)(xiii)(B), beginning with the 2021 MIPS payment year, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out (82 FR 53726 through 53727). As part of our technical updates to § 414.1380(b)(1) outlined in section III.H.3.i.(1)(b) of this proposed rule, our finalized topped out scoring policies are now referenced at § 414.1380(b)(1)(iv).

We refer readers to the 2018 MIPS Quality Benchmarks' file, that is located on the Quality Payment Program resource library (<https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html>) to determine which measure benchmarks are topped out for 2018 and would be subject to the cap if they are also topped out in the 2019 MIPS Quality Benchmarks' file. We note that the final determination of which measure benchmarks are subject to the topped out cap will not be available

until the 2019 MIPS Quality Benchmarks' file is released in late 2018.

We did not propose to apply our previously finalized topped out scoring policy to the CAHPS for MIPS survey (82 FR 53726). Because the CAHPS for MIPS survey was revised in 2018 (82 FR 53632), we do not have historical benchmarks for the 2018 performance period, so the topped out policy would not be applied for the 2019 performance period. Last year, we received limited feedback when we sought comment on how the topped out scoring policy should be applied to CAHPS for MIPS survey. In this proposed rule, we are seeking feedback on potential ways we can score CAHPS for MIPS Summary Survey Measures (SSM). For example, we could score all SSMs, which means there would effectively be no topped out scoring for CAHPS for MIPS SSMs, or we could cap the SSMs that are topped out and score all other SSMs. We seek comment on these approaches and additional approaches to the topped out scoring policy for CAHPS for MIPS SSMs. We note that we would like to encourage groups to report the CAHPS for MIPS survey as it incorporates beneficiary feedback.

(v) Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements

In the CY 2017 Quality Payment Program final rule (81 FR 77288 through 77289), we established scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement. As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.H.3.i.(1)(b) of this proposed rule, our previous scoring policies are now referenced at § 414.1380(b)(1)(i)(A) and (B).

A summary of the current and proposed policies is provided in Table 47. For more of the statutory background and details on current policies, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77288 through 77289 and 82 FR 53727 through 53730, respectively).

TABLE 47—QUALITY PERFORMANCE CATEGORY: SCORING MEASURES

Measure type	Description	Scoring rules
Class 1	For the 2018 and 2019 MIPS performance period: Measures that can be scored based on performance Measures that were submitted or calculated that met the following criteria:	For the 2018 and 2019 MIPS performance period: 3 to 10 points based on performance compared to the benchmark.

TABLE 47—QUALITY PERFORMANCE CATEGORY: SCORING MEASURES—Continued

Measure type	Description	Scoring rules
Class 2	(1) Has a benchmark; (2) Has at least 20 cases; and (3) Meets the data completeness standard (generally 60 percent). For the 2018 and 2019 MIPS performance period: Measures that were submitted and meet data completeness, but do not have both of the following: (1) a benchmark. (2) at least 20 cases.	For the 2018 and 2019 MIPS performance period: 3 points. * This Class 2 measure policy does not apply to CMS Web Interface measures and administrative claims based measures.
Class 3**	For the 2018 and 2019 MIPS performance period: Measures that were submitted, but do not meet data completeness criteria, regardless of whether they have a benchmark or meet the case minimum.	For the 2018 and 2019 MIPS performance period: 1 point except for small practices, which would receive 3 measure achievement points. Beginning with the 2020 MIPS performance period: MIPS eligible clinicians other than small practices will receive zero measure achievement points. Small practices will continue to receive 3 points. * This Class 3 measure policy would not apply to CMS Web Interface measures and administrative claims based measures.

As the MIPS program continues to mature, we are looking to find ways to improve our policies, including what to do with measures that do not meet the case minimum. While many MIPS eligible clinicians can meet the 20-case minimum requirement, we recognize that small practices and individual MIPS eligible clinicians may have difficulty meeting this standard. While we process data from the CY 2017 MIPS performance period to determine how often submitted measures do not meet case minimums, we invite public comment on ways we can improve our case-minimum policy. In determining future improvements to our case minimum policy, our goal is to balance the concerns of MIPS eligible clinicians who are unable to meet the case minimum requirement and for whom we cannot capture enough data to reliably measure performance, while not creating incentives for MIPS eligible clinicians to choose measures that do not meet case minimum even though other more relevant measures are available.

We propose to maintain the policies finalized for the CY 2018 MIPS performance period regarding measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria for the CY 2019 MIPS performance period, and to amend § 414.1380(b)(1)(i) accordingly.

We also propose to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period and to amend § 414.1380(b)(1)(i)(B)(1) accordingly. This policy is part of our effort to move toward complete and accurate reporting that reflects meaningful effort to

improve the quality of care that patients receive. Measures submitted by small practices would continue to receive 3 points for all future CY MIPS performance periods, although we may revisit this policy through future rulemaking.

(vi) Scoring Flexibility for Measures With Clinical Guideline Changes During the Performance Period

In the CY 2018 Quality Payment Program final rule (82 FR 53714 through 53716), we finalized that, beginning with the 2018 MIPS performance period, we will assess performance on measures considered significantly impacted by ICD-10 updates based only on the first 9 months of the 12-month performance period (for example, January 1, 2018, through September 30, 2018, for the 2018 MIPS performance period). We noted that performance on measures that are not significantly impacted by changes to ICD-10 codes would continue to be assessed on the full 12-month performance period (January 1 through December 31). Lastly, we finalized that we will publish the list of measures requiring a 9-month assessment process on the CMS website by October 1st of the performance period if technically feasible, but by no later than the beginning of the data submission period (for example, January 2, 2019, for the 2018 MIPS performance period). As part of our technical updates to § 414.1380(b)(1) outlined in section III.H.3.i.(1)(b) of this proposed rule, these policies are now referenced at § 414.1380(b)(1)(viii).

We remain concerned about instances where clinical guideline changes or other changes to evidence supporting a measure occur during the performance

period that may significantly impact a measure. Clinical guidelines and protocols developed by clinical experts and specialty medical societies often underpin quality measures. At times, measure stewards must amend quality measures to reflect new research and changed clinical guidelines, and sometimes, as a result of the change in these guidelines, adherence to guidelines in the existing measures could result in patient harm or otherwise provide misleading results as to good quality care. We sought comment in the CY 2018 Quality Payment Program final rule regarding whether we should apply scoring flexibility to measures significantly impacted by clinical guideline changes (82 FR 53716).

A few commenters made suggestions. One commenter supported using an approach similar to the one used for measures impacted by ICD-10 changes. One commenter also recommended that the process be evaluated periodically. A few commenters did not support CMS scoring measures with less than 12 months of data because the commenters believed this may result in unsuccessful reporting and could affect the measure logic. One commenter recommended engaging measure developers and/or stewards and measure implementers who may have novel approaches for accounting for ICD-10 and other significant changes, such as releasing new measure guidance or suspending updates to the measure until the following performance period. The commenter also recommended that, for each measure with a significant change, CMS post the proposed approach for scoring the measure on the Quality

Payment Program website for a 30-day public comment period.

We remain concerned that findings of evidence-based research, providing the basis for sound clinical practice guidelines and recommendations that are the foundation of a quality measure, may change outside of the rulemaking cycle. As the clinical evidence and guidelines change, approved measures may no longer reflect the most up-to-date clinical evidence and could be contrary to patient well-being. There may be instances in which changes to clinical guidelines are so significant, that an expedited review is needed outside of the rulemaking cycle because measures may result in a practice that is harmful to patients. To further align with policies adopted within other value based programs such as the Hospital VBP Program (83 FR 20409), we are proposing to suppress a measure without rulemaking, if during the performance period a measure is significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns. CMS would rely on measure stewards for notification in changes to clinical guidelines. We will publish on the CMS website suppressed measures whenever technically feasible, but by no later than the beginning of the data submission period.

We propose policies to provide scoring flexibility in the event that we need to suppress a measure during a performance period. Scoring for a suppressed measure would result in a zero achievement points for the measure and a reduction of the total available measure achievement points by 10 points. We believe that this approach effectively removes the impact of the eligible clinician's inability to receive measure achievement points for the measure, if a submitted measure is later suppressed.

We propose to add a new paragraph at § 414.1380(b)(1)(vii) that beginning with the 2019 MIPS performance period, CMS will reduce the total available measure achievement points for the quality performance category by 10 points for MIPS eligible clinicians that submit a measure significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns.

(vii) Scoring for MIPS Eligible Clinicians That Do Not Meet Quality Performance Category Criteria

In the CY 2018 Quality Payment Program final rule (82 FR 53732), we finalized that, beginning with the 2021 MIPS payment year, we will validate the availability and applicability of quality

measures only with respect to the collection type that a MIPS eligible clinician utilizes for the quality performance category for a performance period, and only if a MIPS eligible clinician collects via claims only, MIPS CQMs only, or a combination of MIPS CQMs and claims collection types. We will not apply the validation process to any data collection type that the MIPS eligible clinician does not utilize for the quality performance category for the performance period. We sought comment on how to modify the validation process for the 2021 MIPS payment year when clinicians may submit measures collected via multiple collection types.

As discussed in section III.H.3.h.(1)(b) of this proposed rule, we are proposing to revise our terminology regarding data submission. This updated terminology will more accurately reflect our current submissions and validation policies. We propose to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen. For example, this policy would not apply to eCQMs even if they are submitted by a registry.

We note that a MIPS eligible clinician may not have available and applicable quality measures. If we are unable to score the quality performance category, then we may reweight the clinician's score according to the reweighting policies described in sections III.H.3.i.(2)(b)(ii) and III.H.3.i.(2)(b)(iii) of this proposed rule.

(viii) Small Practice Bonus

In the CY 2018 Quality Payment Program final rule, we finalized at § 414.1380(c)(4) to add a small practice bonus of 5 points to the final score for the 2020 MIPS payment year for MIPS eligible clinicians, groups, APM Entities, and virtual groups that meet the definition of a small practice as defined at § 414.1305 and submit data on at least one performance category in the 2018 MIPS performance period.

We continue to believe an adjustment for small practices is generally appropriate due to the unique challenges small practices experience related to financial and other resources, as well as the performance gap we have observed (based on historical PQRS data) for small practices in comparison to larger practices. We believe a small practice bonus specific to the quality performance category is preferable for the 2021 MIPS payment year and future years. We believe it is appropriate to apply a small practice bonus points to the quality performance category based on observations using historical data,

which indicates that small practices are less likely to submit quality performance data, less likely to report as a group and use the CMS Web Interface, and more likely to have lower performance rates in the quality performance category than other practices. We want the final score to reflect performance, rather than the ability and infrastructure to support submitting quality performance category data.

We considered whether we should continue to apply the small practice bonus through bonus points in all four performance categories, but believe the need for doing so is less compelling. The improvement activities performance category already includes special scoring for small practices (please refer to § 414.1380(b)(3) and see section III.H.3.i.(1)(e) of this proposed rule for more information). In addition, for the Promoting Interoperability performance category, small practices can apply for a significant hardship exception if they have issues acquiring an EHR (see section III.H.3.h.(5) of this proposed rule). Finally, the cost performance category does not require submission of any data; therefore, there is less concern about a small practice being burdened by those requirements. For these reasons, we are proposing to transition the small practice bonus to the quality performance category.

Starting with the 2021 MIPS payment year, we propose at § 414.1380(b)(1)(v)(C) to add a small practice bonus of 3 points in the numerator of the quality performance category for MIPS eligible clinicians in small practices if the MIPS eligible clinician submits data to MIPS on at least 1 quality measure. Because MIPS eligible clinicians in small practices are not measured on the readmission measure and are not able to participate in the CMS Web Interface, they generally have a quality performance category denominator of 60 total possible measure achievement points. Thus, our proposal of 3 measure bonus points generally represents 5 percent of the quality performance category score. As described in section III.H.3.i.(2)(b)(iii) of this proposed rule, for clinicians in many small practices, the quality performance category weight may be up to 85 percent of the final score. (For example, if a small practice applies for the Promoting Interoperability significant hardship application and does not meet the sufficient case minimum for cost measures then the weights of Promoting Interoperability and cost performance categories are redistributed to quality

and the quality performance category weight would be 85 percent.)

With a weight of 85 percent, a small practice bonus of 3 points added to the quality performance category will result in 4.25 bonus points added to the final score for clinicians in small practices.²⁹ We believe this is appropriate because it is similar to the impact of the small practice bonus we finalized for the 2020 MIPS payment year (5 points added to the final score). While we recognize that the impact of the small practice bonus for MIPS eligible clinicians in small practices who do not receive reweighting for the cost and/or Promoting Interoperability performance categories will be less than 4.25 points added to the final score, we believe a consistent approach is preferable for simplicity, and we do not believe that a larger bonus is appropriate as that could potentially inflate the quality performance category score and the final score and mask poor performance.

(ix) Incentives To Report High-Priority Measures

In the CY 2017 Quality Payment Program final rule, we established a cap on high-priority measure bonus points for the first 2 years of MIPS at 10 percent of the denominator (total possible measure achievement points the MIPS eligible clinician could receive in the quality performance category) of the quality performance category (81 FR 77294). As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.H.3.i.(1)(b) of this proposed rule, our previously established policy on incentives to report high-priority measures is now referenced at § 414.1380(b)(1)(v)(A). We are proposing to maintain the cap on measure bonus points for reporting high-priority measures for the 2021 MIPS payment year, and to amend § 414.1380(b)(1)(v)(A)(i)(ii), accordingly.

We established the scoring policies for high-priority measure bonus points in the CY 2017 Quality Payment Program final rule (81 FR 77293). We noted that, in addition to the required measures, CMS Web Interface reporters may also report the CAHPS for MIPS survey and receive measure bonus points for submitting that measure (81 FR 77293). We refer readers to § 414.1380(b)(1)(v)(A) for more details on the high-priority measure bonus points scoring policies.

For the 2021 MIPS payment year, we propose to modify the policies finalized

in the CY 2017 Quality Payment Program final rule (and amend § 414.1380(b)(1)(v)(A) accordingly) to discontinue awarding measure bonus points to CMS Web Interface reporters for reporting high-priority measures. As we continue to move forward in implementing the MIPS program, we no longer believe that it is appropriate to award CMS Web Interface reporters measure bonus points to be consistent with other policies regarding selection of measures. Based on additional data analyses since the first-year policy was implemented, we have found that practices that elect to report via CMS Web Interface generally perform better than other practices that select other collection types. Therefore, the benefit of the bonus points is limited and instead we believe will create higher than normal scores. Bonus points were created as transition policies which were not meant to continue through the life of the program. Measure bonus points are also used to encourage the selection of additional high-priority measures. As the program matures, we have established other policies related to measures selection, such as applying a cap of 7 measure achievement points if a clinician selects and submits a measure that has been topped out for 2 or more years; however, we have excluded CMS Web Interface reporters from the topped out policies because reporters have no choice in measures. By the same logic, since CMS Web Interface reporters have no choice in measures, we do not believe it is appropriate to continue to provide additional high-priority measure bonuses for reporting CMS Web Interface measures. We note the CMS Web Interface users may still elect to report the CAHPS for MIPS survey in addition to the CMS Web Interface, and if they do, they would receive the high priority bonus points for reporting the survey.

As part of our move towards fully implementing the high value measures as discussed in section III.H.3.h.(2)(b)(iv) of this proposed rule, we believe that bonus points for high priority measures for all collection types may no longer be needed, and as a result, we intend to consider in future rulemaking whether to modify our scoring policy to no longer offer high priority bonus points after the 2021 MIPS payment year.

(x) Incentives To Use CEHRT To Support Quality Performance Category Submissions

Section 1848(q)(5)(B)(ii) of the Act requires the Secretary to encourage MIPS eligible clinicians to report on

applicable quality measures through the use of CEHRT. Under § 414.1380(b)(1)(xv), 1 bonus point is available for each quality measure submitted with end-to-end electronic reporting, under certain criteria. As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.H.3.i.(1)(b) of this proposed rule, our previously established electronic end-to-end reporting bonus point scoring policy is now referenced at § 414.1380(b)(1)(v)(B).

We are proposing to maintain the cap on measure bonus points for reporting high-priority measures for the 2021 MIPS payment year. We also propose to continue to assign bonus points for end-to-end electronic reporting for the 2021 MIPS payment year, as we have seen that this policy encourages electronic reporting. We propose to amend § 414.1380(b)(1)(v)(B) accordingly.

We also are proposing to modify our end-to-end reporting bonus point scoring policy based on the proposed changes to the submission terminology discussed in section III.H.3.h.(1)(b) of this proposed rule. We propose that the end-to-end reporting bonus can only apply to the subset of data submitted by direct, log in and upload, and CMS Web Interface that meet the criteria finalized in the CY 2017 Quality Payment Program final rule (81 FR 77297 through 77298). However, the end-to-end reporting bonus would not be applied to the claims submission type because it does not meet the criteria discussed above. This is not a policy change but rather a clarification of our current process in light of the proposed terminology changes.

As discussed in section III.H.3.i.(1)(b)(x) of this proposed rule, we believe that in the future bonus points for end-to-end reporting for all submission types will no longer be needed as we move towards fully implementing the program, and as a result we intend to consider in future rulemaking modifying our scoring policy to no longer offer end-to-end reporting bonus points after the 2021 MIPS payment year. Consistent with the section 1848(q)(5)(B)(ii) of the Act, which requires the Secretary to encourage the use of CEHRT for quality reporting, we will continue to be committed to ways that we can incentivize and encourage these reporting methods. We invite comment on other ways that we can encourage the use of CEHRT for quality reporting.

²⁹ We get 4.25 points using the following calculation: (3 measure bonus point/60 total measure points) * 85 percent * 100 = 4.25.

(xi) Calculating Total Measure Achievement and Measure Bonus Points
(A) Calculating Total Measure Achievement and Measure Bonus Points for Non-CMS Web Interface Reporters

In the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77300, and 82 FR 53733 through 53736, respectively), we established the policy for calculating total measure achievement and measure bonus points for Non-CMS Web Interface reporters. We refer readers to § 414.1380(b)(1) for more details on these policies.

We are not proposing any changes to the policy for scoring submitted measures collected across multiple

collection types; however, we provide a summary of how this policy will be scored using our new terminology. We note that CMS Web Interface and facility-based measurement each have a comprehensive set of measures that meet the proposed MIPS category requirements. As a result, we did not combine CMS Web Interface measures or facility-based measurement with other ways groups can be scored for data submitted for MIPS (other than CAHPS for MIPS, which can be submitted in conjunction with the CMS Web Interface). We refer readers to section III.H.3.i.(1)(d) of this proposed rule for a description of our policies on facility-based measurement.

Although we have established a policy to account for scoring in circumstances when the same measure is collected via multiple collection types, we anticipate that this will be a rare circumstance and do not encourage clinicians to submit the same measure collected via multiple collection types. Table 48 is included in this proposed rule for illustrative purposes and clarity due to the changes in terminology discussed in section III.H.3.h.(1)(b) of this proposed rule. For further discussion of this example, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53734).

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TABLE 48: Example Assigning Total Measure Achievement and Bonus Points for an Individual MIPS Eligible Clinician Who Submits Measures Collected Across Multiple Collection Types

	Measure Achievement Points	Six Scored Measures	High-Priority Measure Bonus Points	Incentive for CEHRT Measure Bonus Points
<i>MIPS CQMs</i>				
Measure A (Outcome)	7.1	7.1 (Outcome measure with highest achievement points)	(required outcome measure does not receive bonus points)	
Measure B	6.2 (points not considered because it is lower than the 8.2 points for the same claims measure)			
Measure C (high priority patient safety measure that meets requirements for additional bonus points)	5.1 (points not considered because it is lower than the 6.0 points for the same claims measure)		1	
<i>Claims</i>				
Measure A (Outcome)	4.1 (points not considered because it is lower than the 7.1 points for the same MIPS CQM)		No bonus points because the MIPS CQM of the same measure satisfies requirement for outcome measure.	
Measure B	8.2	8.2		
Measure C (High priority patient safety measure that meets requirements for additional bonus points)	6.0	6.0	No bonus (Bonus applied to the MIPS CQMs)	
Measure D (outcome measure <50% of data submitted)	1.0		(no high priority bonus points because below data completeness)	
<i>EHR (direct submission using end-to-end)</i>				
Measure E	5.1	5.1		1
Measure F	5.0	5.0		1
Measure G	4.1			1
Measure H	4.2	4.2		1

	Measure Achievement Points	Six Scored Measures	High-Priority Measure Bonus Points	Incentive for CEHRT Measure Bonus Points
Measure I (high priority patient safety measure that is below case minimum)	3.0		(no high priority bonus points because below case minimum)	1
		35.6	1 (below 10% cap ¹)	5 (below 10% cap)
Quality Performance Category Percent Score Prior to Improvement Scoring		$(35.6 + 1 + 5) / 60 = 69.33\%$		

¹ In this example, the cap would be 6 points, which is 10 percent of the total available measure achievement points of 60.

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We do not propose any changes to our policy regarding scoring measure achievement points and bonus points when using multiple collection types for non-Web Interface MIPS eligible clinicians in the quality performance category for the 2019 MIPS performance period.

(B) Calculating Total Measure Achievement and Measure Bonus Points for CMS Web Interface Reporters

In the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77302 through 77306, and 82 FR 53736 through 82 FR 53737, respectively), we finalized the scoring policies for CMS Web Interface reporters. As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.H.3.i.(1)(b) of this proposed rule, our previously established policies for CMS Web Interface reporters are now referenced at § 414.1380(b)(1)(i)(A)(2)(i) and (b)(1)(v)(A).

(xii) Future Approaches to Scoring the Quality Performance Category

As we discuss in section III.H.3.h.(2)(b)(iv) of this proposed rule, we anticipate making changes to the quality performance category to reduce burden and increase the value of the measures we are collecting. We discussed that existing measures have differing levels of value and our approaches for implementing a system where points are awarded based on the value of the measure. Should we adopt these approaches, we anticipate needing to modify our scoring approaches accordingly. In addition, we have received stakeholder feedback asking us to simplify scoring for the quality performance category. Therefore, we are seeking comment on the following approaches to scoring that we may

consider in future rulemaking and whether these approaches move the clinicians towards reporting high value measures and more accurate performance measurement.

One option for simplification is restructuring the quality requirements with a pre-determined denominator, for example, 50 points, but no specific requirements regarding the number of measures that must be submitted. Further, we would categorize MIPS and QCDR measures by value, because we recognize that not all measures are created equal. We seek to ensure that the collection and submission of data is valuable to clinicians and worth the cost and burden of collection of information. A system to classify measures as a particular value (for example, gold, silver, or bronze) is discussed in section III.H.3.h.(2)(b)(iv) of this proposed rule. In this approach, the highest tier would include measures that are considered “gold” standard, such as outcome measures, composite measure, or measures that address agency priorities (such as opioids). The CAHPS for MIPS survey, which collects patient experience data, may also be considered a high-value measure. Measures considered in the second tier, or at a “silver” standard, would be process measures that are directly related to outcomes and have a good gap in performance (there is no high, unwavering performance) and demonstrate room for improvement, or topped out outcome measures. Lower value measures, such as standard of care process measures or topped out process measures, would have scoring caps in place that would reflect the measure’s status as a “bronze measure.” In this scenario, we could envision awarding points for achievement as follows: up to 15 to 20 points in the top tier; up to 10 points in the next tier; and up to 5

points in the lowest tier. Similar to the structure of the improvement activities performance category, a clinician that chooses a top-tier measure would not have to submit as many measures to MIPS. We would still want to ensure the submission of high value measures and might include requirements that restrict the number of lower tier measures that could be submitted; alternatively, we could add a requirement that a certain number of higher tier measures would need to be submitted. With this approach, we could still incentivize reporting on high-priority measures by classifying them as “gold” standard measures which would be eligible for up to 15 to 20 achievement points.

Alternatively, we could keep our current approach for the quality performance category requiring 6 measures including one outcome measure, with every measure worth up to 10 measure achievement points in the denominator, but change the minimum number of measure achievement points available to vary by the measure tier. For example, high-tier measures could qualify for high priority bonus and/or have a higher potential floor (for example, 5 measure achievement points instead of the floor of 3 measure achievement points for “gold” standard measures, which would be eligible for up to 10 measure achievement points.); whereas low-tier measures could have a lower floor (for example, 1 measure achievement point instead of the floor of 3 measure achievement points for “bronze standard” measures).

Taking into consideration the potential future quality performance category change, we also believe that removing the validation process to determine whether the eligible clinician has measures that are available and applicable would simplify the quality performance category significantly.

Several stakeholders expressed their confusion with the validation process. A move to sets of measures in the quality performance category, potentially with some criteria to define the clinicians for whom these measures are applicable, would eliminate the need for a validation process for measures that are available and applicable. Moving to sets of measures would also enable us to develop more robust benchmarks. We also believe that in the next few years, we could remove the validation process for measures that are available and applicable if we set the denominator at a pre-determined level (as outlined in the example above at 50 points) and let clinicians determine the best method to achieve 50 points.

For the 2019 and 2020 MIPS payment years, MIPS eligible clinicians and groups who report on QCDR measures that do not have an available benchmark based on the baseline or performance period but meet data completeness are assigned a score of 3 measure achievement points (small practices receive 3 points regardless of whether they meet data completeness). Through stakeholder engagement, particularly feedback provided by QCDRs who have developed their own measures, we have heard that MIPS eligible clinicians are hesitant to report QCDR measures without established benchmarks. Eligible clinicians have voiced concern on reporting on QCDR measures without benchmarks because they are not certain that a benchmark could be calculated and established for the MIPS performance period, and they would therefore be limited to a 3-point score for that QCDR measure. In addition, QCDRs have inquired about the possibility of creating QCDR benchmarks. To encourage reporting of QCDR measures, we seek comment on an approach to develop QCDR measure benchmarks based off historical measure data. This may require QCDRs to submit historical data in a form and manner that meets benchmarking needs as required by CMS. We anticipate that the historical QCDR measure data would need to be submitted at the time of self-nomination of the QCDR measure, during the self-nomination period. Detailed discussion of the self-nomination period timeline and requirements can be found in section III.H.3.k of this proposed rule. Our concern with utilizing historical data provided by QCDRs to develop benchmarks is whether QCDRs have the capability to filter through their historical measure data to extract only data from MIPS eligible clinicians and groups prior to submitting the historical

data to CMS for QCDR measure benchmarking consideration. Furthermore, once the historical data is submitted by the QCDR, CMS would analyze the data to ensure that it met benchmarking standards prior to it being accepted to form a benchmark. However, to perform this analysis CMS may need additional data elements such as the sources of the data, data completeness, and the collection period. In addition to seeking comment on developing QCDR measure benchmarks from historical data, we also seek comment as to how our aforementioned concerns may be addressed for future rulemaking.

We also recognize that improving the electronic capture, calculation, and reporting of quality measures is also an important component of reducing provider burden. We invite comment on how we can incorporate incentives for the use of electronic clinical quality measurement into the future approaches described under this section, as well as other ways to encourage more efficient technology-enabled measurement approaches.

We seek comment on these approaches and other approaches to simplify scoring, provide incentives to submit more impactful measures that assess outcomes rather than processes, and develop data that can show differences in performance and determine clinicians that provide high value care.

(xiii) Improvement Scoring for the MIPS Quality Performance Category Percent Score

Section 1848(q)(5)(D)(i) of the Act stipulates that, beginning with the second year to which the MIPS applies, if data sufficient to measure improvement is available, the improvement of the quality performance category score for eligible clinicians should be measured. To measure improvement we require a direct comparison of data from one Quality Payment Program year to another (82 FR 52740). For more descriptions of our current policies, we refer readers to the CY 2018 Quality Payment Program proposed and final rule (82 FR 53737 to 53747). As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.H.3.i.(1)(b) of this proposed rule, our previously established improvement scoring policies are now referenced at § 414.1380(b)(1)(vi).

In the CY 2018 Quality Payment Program final rule, we adopted a policy that MIPS eligible clinicians must fully participate to receive a quality performance category improvement

percent score greater than zero (82 FR 53743 through 53745). In § 414.1380(b)(1)(vi)(F), we determined “participation” to mean compliance with § 414.1330 and § 414.1340 in the current performance period. We issued a technical correction for the CY 2018 Quality Payment Year final rule, replacing § 414.1330 with § 414.1335 since § 414.1335 is more specific because it discusses the quality performance category requirements.

We finalized at § 414.1380(b)(1)(vi)(C)(4) that we would compare the 2018 performance to an assumed 2017 quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year (82 FR 53744 through 53745). We propose to continue this policy for the 2019 MIPS performance period and amend § 414.1380(b)(1)(vi)(C)(4), accordingly. We propose to compare the 2019 performance to an assumed 2018 quality performance category achievement percent score of 30 percent.

(xiv) Calculating the Quality Performance Category Percent Score Including Achievement and Improvement Points

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77300 and 82 FR 53747 through 53748, respectively), we finalized the policies on incorporating the improvement percent score into the quality performance category percent score. As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.H.3.i.(1)(b) of this proposed rule, our previously established policies are now referenced at § 414.1380(b)(1)(vii).

(c) Scoring the Cost Performance Category

(i) Scoring Achievement in the Cost Performance Category

For a description of the statutory basis and our existing policies for scoring achievement in the cost performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77311) and the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53749). In the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77309), we established that we will determine cost measure benchmarks based on cost measure performance during the performance period. We also established that at least 20 MIPS eligible clinicians or groups must meet the minimum case volume that we specify

for a cost measure in order for a benchmark to be determined for the measure, and that if a benchmark is not determined for a cost measure, the measure will not be scored. We propose to codify these final policies at § 414.1380(b)(2)(i).

(ii) Scoring Improvement in the Cost Performance Category

For a description of the statutory basis and our existing policies for scoring improvement in the cost performance category, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53749 through 53752). Section 51003(a)(1)(B) of the Bipartisan Budget Act of 2018 modified section 1848(q)(5)(D) of the Act such that the cost performance category score shall not take into account the improvement of the MIPS eligible clinician for each of the second, third, fourth, and fifth years for which the MIPS applies to payments. We do not believe this change requires us to remove our existing methodology for scoring improvement in the cost performance category (see 82 FR 53749 through 53752), but it does prohibit us from including an improvement component in the cost performance category percent score for each of the 2020 through 2023 MIPS payment years. Therefore, we propose to revise § 414.1380(b)(2)(iv)(E) to provide that the maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points. Under our existing policy (82 FR 53751 through 53752), the maximum cost improvement score for the 2020 MIPS payment year is 1 percentage point, but due to the statutory changes and under our proposal, the maximum cost improvement score for the 2020 MIPS payment year would be zero percentage points. We are also proposing at § 414.1380(a)(1)(ii) to modify the performance standards to reflect that the cost performance category percent score will not take into account improvement until the 2024 MIPS payment year.

(d) Facility-Based Measures Scoring Option for the 2021 MIPS Payment Year for the Quality and Cost Performance Categories

(i) Background

In the CY 2018 Quality Payment Program final rule, we established a facility-based measurement scoring option for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year (82 FR 53752 through 53767). We originally proposed a facility-based measurement scoring

option for the 2018 MIPS performance period. We did not finalize the policy because we were concerned that we would not have the operational ability to inform clinicians early enough in the 2018 MIPS performance period to allow them to consider the consequences and benefits of participation (82 FR 53755).

(ii) Facility-Based Measurement Applicability

(A) General

In the CY 2018 Quality Payment Program final rule, we limited facility-based reporting to the inpatient hospital in the first year for several reasons, including that a more diverse group of clinicians (and specialty types) provide services in an inpatient setting than in other settings, and that the Hospital Value-Based Purchasing (VBP) Program adjusts payment to hospitals in connection with both increases and decreases in performance (82 FR 53753 through 53755). We also limited measures applicable for facility-based measurement to those used in the Hospital VBP Program because the Hospital VBP Program compares hospitals on a series of different measures intended to capture the breadth of inpatient care in the facility (82 FR 53753). We noted that we were open to the consideration of additional facility types in the future but recognized that adding a facility type would be dependent upon the status of the VBP program applicable to that facility, the applicability of measures, and the ability to appropriately attribute a clinician to a facility (82 FR 53754). We do not propose to add additional facility types for facility-based measurement in this proposed rule, but we are interested in potentially expanding to other settings in future rulemaking. Therefore, in section III.H.3.i.(1)(d)(vii), we outline several issues that would need to be resolved in order to expand this option to a wider group of facility-based clinicians.

(B) Facility-Based Measurement by Individual Clinicians

In the CY 2018 Quality Payment Program final rule, we established individual eligibility criteria for facility-based measurement at § 414.1380(e)(2)(i). We established that a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital or emergency room based on claims for a period prior to the performance period as specified by CMS (82 FR 53756 through 53757) is eligible

as an individual for facility-based measurement. We had noted, as a part of our proposal summary, that we would use the definition of professional services in section 1848(k)(3)(A) of the Act in applying this standard (82 FR 53756). For purposes of determining eligibility for facility-based measurement, we discussed CMS using data from the period between September 1 of the calendar year, 2 years preceding the MIPS performance period, through August 31 of the calendar year preceding the MIPS performance period, with a 30-day claims run out but did not finalize that as part of the applicable regulation (82 FR 53756 through 53757). Because we are using the quality measures associated with the inpatient hospital to determine the MIPS quality and cost performance category score, we wanted to ensure that eligible clinicians contributed to care in that setting during that time period.

We indicated that CMS will use POS code 21 (inpatient) and POS code 23 (emergency department) for this purpose (82 FR 53756). Commenters on our proposal (as summarized in the CY 2018 Quality Payment Program final rule (82 FR 53756 through 53757)) expressed concern that adopting the definition that we did for facility-based clinicians would limit the number of clinicians who would be eligible. In particular, commenters were concerned about the omission of the on-campus outpatient hospital POS code (POS code 22) for observation services, which are similar to and often take place in the same physical location as inpatient services. In the CY 2018 Quality Payment Program final rule, we sought comment on ways to identify clinicians who have a significant presence within the inpatient setting, and how to address concerns about including POS code 22 in this definition (82 FR 53757). A few commenters that responded again suggested that CMS add POS code 22. In addition, a few commenters suggested that several other POS can be included, including ambulatory surgical centers, IRFs, and SNFs.

We are proposing to modify our determination of a facility-based individual at § 414.1380(e)(2)(i) in four ways. First, we propose to add on-campus outpatient hospital (as identified in the POS code in the HIPAA standard transaction, that is, POS code 22) to the settings that determine whether a clinician is facility-based. Second, we propose that a clinician must have at least a single service billed with the POS code used for the inpatient hospital or emergency room. Third, we propose that, if we are unable to identify a facility with a VBP score

to attribute a clinician's performance, that clinician is not eligible for facility-based measurement. Fourth, we propose to align the time period for determining eligibility for facility-based measurement with changes to the dates used to determine MIPS eligibility and special status detailed in section III.H.3.b. of this rule. We explain these four proposals below. We believe that these proposals will further expand the opportunity for facility-based measurement and eliminate issues associated with the provision of observation services while still restricting eligibility to those who work in an inpatient setting.

First, we propose to add the on-campus outpatient hospital (POS code 22) to the list of sites of service used to determine eligibility for facility-based measurement. We agree with commenters that limiting the eligibility to our current definition may prevent some clinicians who are largely hospital-based from being eligible. However, expanding eligibility without taking into account the relationship between the clinician and the facility and facility's performance could result in unfairly attributing to a clinician performance for which the clinician is not responsible or has little to no role in improving. We do believe that a significant provision of services in the on-campus outpatient hospital are reflected in the quality captured by the Hospital VBP Program. For example, patients in observation status are typically treated by the same staff and clinicians as those who meet the requirements for inpatient status. While there are some clinical differences that may result in a patient having observation status, we believe that the quality of care provided to these patients in this same setting would be comparable, reflecting the overall healthcare system at that particular location. Therefore, we are convinced that a sufficient nexus exists for attributing the hospital's VBP performance to clinicians that provide services in on-campus outpatient hospital settings.

Second, we propose to require that clinicians bill at least a single service with the POS codes for inpatient hospital or the emergency room in order to be eligible for facility-based measurement. While we generally believe that clinicians who provide services in the outpatient hospital can affect the quality of care for inpatients, we believe that a clinician who is to be measured according to the performance of a hospital should at least have a minimal presence in the inpatient or emergency room setting. We remain

concerned about including clinicians who provide at least 75 percent of their services at on-campus outpatient hospitals (with POS code 22) when such clinicians exclusively provide outpatient services that are unrelated to inpatient hospital service. For example, a dermatologist who provides office-based services in a hospital-owned clinic but who never admits or treats patient within the inpatient or emergency room setting does not meaningfully contribute to the quality of care for patients measured under the Hospital VBP Program.

We considered different ways to best identify those who contribute to the quality of care in the inpatient setting while keeping the facility-based scoring option as simple as possible. We considered separately measuring the HCPCS codes for observation services, but believe that such a measurement may not fairly consider services provided by clinicians for whom observations services may be embedded in a global code for a procedure rather than billed as a separate observation service. We also considered requiring a clinician to provide a certain percentage of services with the inpatient hospital POS. However, we have not identified a threshold (other the one claim threshold we proposed here) that would more meaningfully differentiate clinicians who provide services with the outpatient hospital POS code but do not contribute to the services that would be measured under the Hospital VBP Program. We believe it is important to ensure that the program rules are clear and easily applied to clinicians, so as to both avoid confusion on program participation requirements and to meet overall agency goals to increase transparency in the agency's activities. We believe that using a single service as the threshold provides a simple, bright-line to differentiate those who never provide inpatient services from clinicians that do provide inpatient services, as well as outpatient services. We also believe this will limit the opportunity for clinicians who exclusively practice in the outpatient setting to be measured on the VBP performance of an unrelated hospital. We recognize this requirement of one service with the inpatient or emergency department POS may not demonstrate a significant presence in a particular facility, and we seek comment on whether a better threshold could be used to identify those who are contributing to the quality of care for patients in the inpatient setting without creating barriers to eligibility for facility-based measurement.

Our rationale and reasoning for these first two proposals is based in large part on our analysis of the previously finalized policy for eligibility for the facility-based measurement scoring option. Using claims data, we identified all clinicians that would be MIPS eligible as either an individual or group, and identified the POS codes submitted for physician fee schedule services provided by those clinicians. We then modeled the existing final policy based on inpatient and ER services. We determined that while almost all ER physicians would be scored under facility-based measurement, a relatively small percentage of clinicians in other specialties, even those which we would expect to have significant presence in the hospital, would be eligible for the facility-based measurement scoring option. For example, only 13.45 percent of anesthesiologists would be eligible for the facility-based measurement scoring option under our existing policy. Adding the on-campus outpatient hospital POS code substantially increases eligibility for the facility-based measurement scoring option, even after we adjust for requiring one service with the inpatient or emergency department POS. By adopting our newly proposed policy, 72.55 percent of anesthesiologists would be eligible. However, this proposed new policy would not substantially increase the number of clinicians eligible for the facility-based measurement scoring option who, based on specialty identification, may not have a significant presence in the hospital. For example, our newly proposed policy would increase the percentage of family physicians eligible for the facility-based measurement scoring option from 11.34 percent to 13.86 percent, which is still a very small percentage of those clinicians.

Our third proposal is to add a new criterion (To be codified at § 414.1380(e)(2)(i)(C)): To be eligible for facility-based measurement, we must be able to attribute a clinician to a particular facility that has a VBP score. For facility-based measurement to be applicable, we must be able to attribute a clinician to a facility with a VBP score. Based on our definition of facility-based measurement, this means a clinician must be associated with a hospital with a Hospital VBP Program Total Performance Score. We are concerned that our proposed expansion of eligibility for facility-based measurement could increase the number of clinicians who are eligible for facility-based measurement but whom we are unable to attribute to a particular facility

that has a VBP score. In the CY 2018 Quality Payment Program final rule, we noted that some hospitals do not have a Hospital VBP Program Total Performance Score that could be used to determine a MIPS quality and cost performance category score, such as hospitals in the state of Maryland (82 FR 53766). Hence, clinicians associated with those hospitals would not be able to use facility-based measurement but could report quality measures through another method and have cost measures calculated if applicable. We believe a similar result should apply if we cannot attribute a clinician identified as facility-based to a specific facility. We believe that such a situation would be relatively rare. Those clinicians who are identified as facility-based but for whom we are unable to attribute to a hospital must participate in MIPS quality reporting through another method, or they will receive a score of zero in the quality performance category. We therefore propose to add the requirement to § 414.1380(e)(2)(i) that a clinician must be able to be attributed to a particular facility with a VBP score under the methodology specified in § 414.1380(e)(5) to meet eligibility for facility-based measurement. The cross-reference to paragraph (e)(5) is to the methodology for determining the applicable facility score that would be used. Our proposed new regulatory text at § 414.1380(e)(2)(i)(C) addresses both attribution to a facility and the need for that facility to have a VBP score by conditioning eligibility for facility-based scoring for an individual clinician on the clinician being attributed under the methodology in paragraph (e)(5) to a facility with a VBP score.

Fourth, we propose to change the dates of determining eligibility for facility-based measurement. In section III.M.3.b. of this rule, we propose to modify the dates of the MIPS determination period that would provide eligibility determination for small practice size, non-patient facing, low-volume threshold, ASC, hospital-based, and facility-based determination periods. To align this regulation with these other determination periods, we propose that CMS will use data from the initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period with a 30-day claims run out in determining eligibility for facility-based measurement.

(C) Facility-Based Measurement by Group

In the CY 2018 Quality Payment Program final rule, we finalized at § 414.1380(e)(2)(ii) that a MIPS eligible clinician is eligible for facility-based measurement under MIPS if they are determined to be facility-based as part of a group (82 FR 53757). We established at § 414.1380(e)(2)(ii) that a facility-based group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements at § 414.1380(e)(2)(i) (82 FR 53758). We do not propose any changes to the determination of a facility-based group but acknowledge that our proposal to change how individual clinicians are determined to be eligible for facility-based measurement will necessarily have a practical impact for practice groups. For more of the statutory background and descriptions of our current policies on determining a facility-based group, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53757 through 53758).

(iii) Facility Attribution for Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule, we finalized at § 414.1380(e)(5) a method to identify the hospital whose scores would be associated with a MIPS eligible clinician or group that elects facility-based measurement scoring (82 FR 53759). Although we did not specifically address the issue of how facility-based groups would be assigned to a facility (for purposes of attributing facility performance to the group) in the preamble of the CY 2018 Quality Payment Program proposed rule, our proposed regulation at § 414.380(e)(5) did apply the same standard to individuals and groups. We believe that this provided sufficient notice of the policy; nevertheless, we indicated we would address this issue as part of the next Quality Payment Program rulemaking cycle (82 FR 53759). Therefore, we are revisiting facility-based attribution for individuals and groups in this proposed rule.

Under the current regulation text § 414.1380(e)(5), a facility-based clinician or group receives a score under the facility-based measurement scoring standard derived from the VBP score for the facility at which the clinician or group provided services to the most Medicare beneficiaries during the year claims are drawn (that is, the 12-month period described in paragraph (e)(2)). If an equal number of Medicare beneficiaries are treated at more than

one facility, then we will use the VBP score for the highest-scoring facility (82 FR 53759 through 53760). For more of the statutory background and descriptions of our current policies for attributing a facility to a MIPS eligible clinician, we refer readers to the CY 2018 Quality Payment Program final (82 FR 53759 through 53760).

In considering the issue of facility attribution for a facility-based group, we believe that a change to facility-based attribution is appropriate to better align the policy with the determination of a facility-based group at § 414.1380(e)(2)(ii). A facility-based group is one in which 75 percent or more of the eligible clinician NPIs billing under the group's TIN are eligible for facility-based measurement as individuals. Additionally, under the current regulation, the VBP score for the highest scoring facility would be used in the case of a tie among the number of facilities at which the group provided services to Medicare beneficiaries. We propose to revise § 414.1380(e)(5) to differentiate how a facility-based clinician or group receives a score based on whether they participate as a clinician or a group.

We propose to remove "or group" from § 414.1380(e)(5) and redesignate that paragraph as (e)(5)(i) so that it only applies to individual MIPS eligible clinicians. Under our proposal, newly redesignated paragraph (e)(5)(i) retains the rule for facility attribution for an individual MIPS eligible clinician as finalized in the CY 2018 Quality Payment Program final rule; we are also proposing a few minor edits to the paragraph for grammar and to improve the sentence flow. We also propose to add a new paragraph (e)(5)(ii) to provide that a facility-based group receives a score under the facility-based measurement scoring standard derived from the VBP score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under the methodology described in § 414.1380(e)(5)(i) if the clinicians had been scored under facility-based measurement as individuals. We make this proposal because we wish to emphasize the connection between an individual clinician and a facility. We believe that using the plurality of clinicians reinforces the connection between an individual clinician and facility and is more easily understandable for larger groups.

(iv) No Election of Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule, we did not finalize

our proposal for how individual MIPS eligible clinicians or groups who wish to have their quality and cost performance category scores determined based on a facility's performance would elect to do so through an attestation (82 FR 53760). We did finalize, and reflect in the introductory text at § 414.1380(e), that an individual clinician or group would elect to use a facility-based score. The proposal had specified that such clinicians or groups would be required to submit their election during the data submission period through the attestation submission mechanism established for the improvement activities and the Promoting Interoperability performance categories (82 FR 53760). An alternative approach, which likewise was not finalized, did not require an election process, but instead would have automatically applied a facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement, if such an application were technically feasible (82 FR 53760). We noted in the CY 2018 Quality Payment Program final rule that we would examine both the attestation process we proposed and the alternative opt-out process, and work with stakeholders to identify a new proposal in future rulemaking (82 FR 53760). We indicated our interest in a process that would impose less burden on clinicians than an attestation requirement.

In the CY 2018 Quality Payment Program final rule, we requested further comment on the propriety of automatically assigning a clinician or group a score under facility-based measurement, but where CMS would notify and give the clinician the opportunity to opt-out of facility-based measurement (82 FR 53760). We subsequently received comments both in favor of and opposed to an opt-out approach. A few commenters supported the opt-out approach because it would reduce administrative burden on behalf of the clinician. A few commenters expressed concern that an opt-out process could result in clinicians unintentionally being measured on the basis of a facility. A few commenters expressed concern that an automatic assignment of a score would provide an unfair advantage for facility-based clinicians.

After further considering the advantages and disadvantages of an opt-in or an opt-out process, we are proposing a modified policy that does not require an election process. Instead, we propose to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement

and who would benefit by having a higher combined quality and cost performance category score. That is, if the MIPS eligible clinician or group is eligible for facility-based measurement, we would calculate a combined quality and cost performance category score. We propose to use the facility-based score to determine the MIPS quality and cost performance category scores, unless we receive another submission of quality data for or on behalf of that clinician or group and the combined quality and cost performance category score for the other submission results in a higher combined quality and cost performance score. If the other submission has a higher combined quality and cost performance score, then we would not apply the facility-based performance scores for either the quality or cost performance categories. Under our proposal, the combined score for the quality and cost performance categories would determine the scores to be used for both the quality and cost performance categories, for both individual clinicians and for groups that meet the requirements of paragraph (e)(2). We do not propose to adopt a formal opt-out process because, under our proposal, the higher of the quality and cost performance scores available or possible for the clinician or clinician group would be used, which would only benefit the clinician or group. We have a strong commitment to reducing burden as part of the Quality Payment Program, and we believe that requiring a clinician or group to elect a measurement process (or to opt-out of a measurement process) based on facility performance would add unnecessary burden.

In MIPS, we score clinicians as individuals unless they submit data as a group. We believe that same policy should apply to facility-based measurement, even though there are no submission requirements for the quality performance category for individuals under facility-based measurement. Therefore, we propose to revise § 414.1380(e)(4) to state that there are no submission requirements for individual clinicians in facility-based measurement but a group must submit data in the improvement activities or Promoting Interoperability performance categories in order to be measured as a group under facility-based measurement. If a group does not submit improvement activities or Promoting Interoperability measures, then we would apply facility-based measurement to the individual clinicians and such clinicians would not be scored as a group. In the case of virtual groups, MIPS eligible clinicians

would have formed virtual groups prior to the MIPS performance period; as a result, virtual groups eligible for facility-based measurement would always be measured as a virtual group. While we could calculate a score for a TIN without the submission of data by the TIN, we would be uncertain if the clinicians within that group wished to be measured as a group without an active submission (in other words, if the group did not submit data as a group). Submission of data on the improvement activities or Promoting Interoperability measures indicates an intent and desire to be scored as a group. Hence, we believe that using the choice to submit data as a group to identify a group in the context of facility-based scoring will preserve choices made by clinicians and groups while avoiding the burden of an election process to be scored as a group solely for the purpose of facility-based scoring. We solicit comment specifically on this proposal and other means to achieve the same ends.

In the CY 2018 Quality Payment Program final rule, we established that if a clinician or group elects facility-based measurement but also submits MIPS quality data, then the clinician or group would be measured on the method that results in the higher quality score (82 FR 53767). We propose to adopt this same scoring principle in conjunction with our proposal not to use (or require) an election process. Therefore, we propose at § 414.1380(e)(6)(vi) that the MIPS quality and cost score for clinicians and groups eligible for facility-based measurement will be based on the facility-based measurement scoring methodology described in § 414.1380(e)(6) unless the clinician or group receives a higher combined score for the MIPS quality and cost performance categories through data submitted to CMS for MIPS. Because § 414.1380(d) states that MIPS eligible clinicians in MIPS APMs are scored under the MIPS APM scoring standard described at § 414.1370, those clinicians would not be scored using facility-based measurement.

We also propose conforming changes in two other sections of regulatory text. We propose to revise the introductory text at § 414.1380(e) to remove "elect to," and therefore, reflect that clinicians and groups who are determined to be facility-based will receive MIPS quality and cost performance categories under the methodology in paragraph (e). We note that because we do not require clinicians to opt-in into facility-based measurement, there may be clinicians that will continue to submit data via other methods. Hence, these clinicians

and groups are not prohibited from submitting quality measures to CMS for purposes of MIPS; if higher combined quality and cost scores are achieved using data submitted to CMS for purposes of MIPS, then we will use that result. We also propose to revise § 414.1380(e)(4) and (e)(6)(v)(A) to reflect that facility-based measurement does not require election and to replace the phrase “clinicians that elect facility-based measurement” with “clinicians and groups scored under facility-based measurement.”

(v) Facility-Based Measures

(A) Background

Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use measures used for payment systems other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories. However, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. In the CY 2018 Quality Payment Program proposed rule, we proposed to include for the 2020 MIPS payment year all the measures adopted for the FY 2019 Hospital VBP Program on the MIPS list of quality measures and cost measures for purposes of facility based measurement (82 FR 30125). We noted how these measures meet the definition of additional system-based measures provided in section 1848(q)(2)(C)(ii) of the Act (82 FR 30125). In the CY 2018 Quality Payment Program final rule, we did not finalize our proposal that the facility-based measures available for the 2018 MIPS performance period would be the measures adopted for the FY 2019 Hospital VBP Program; nor did we finalize our proposal that, for the 2020 MIPS payment year, facility-based individual MIPS eligible clinicians or groups that were attributed to a facility would be scored on all measures on which the facility is scored via the Hospital VBP Program’s Total Performance Score methodology (82 FR 53762).

We did finalize a facility-based measurement scoring standard but not the specific instance of using the FY 2019 Hospital VBP Program Total Performance Score methodology (82 FR 53755). We expressed our belief that the policy approach of using all measures from the Hospital VBP program is appropriate; nevertheless, because we did not finalize the facility-based measurement scoring option for the 2018 MIPS performance period/2021

MIPS payment year, it was not appropriate to adopt these policies at that time (82 FR 53762 through 53763). We noted that we intended to propose measures that would be available for facility-based measurement for the 2019 MIPS performance period/2021 MIPS payment year in future rulemaking (82 FR 53763).

For a detailed description of the policies proposed and finalized, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53761 through 53763).

(B) Measures in Facility-Based Scoring

We continue to believe it is appropriate to adopt all the measures for the Hospital VBP Program into MIPS for purposes of facility-based scoring; these Hospital VBP Program measures meet the definition of additional system-based measures provided in section 1848(q)(2)(C)(ii) of the Act. We also believe it is appropriate to adopt the performance periods for the measures, which generally are consistent with the dates that we use to determine eligibility for facility-based measurement.

Therefore, beginning with the 2019 MIPS performance period, we propose at § 414.1380(e)(1)(i) to adopt for facility-based measurement, the measure set that we finalize for the fiscal year Hospital VBP program for which payment begins during the applicable MIPS performance period. For example, for the 2019 MIPS performance period, which runs on the 2019 calendar year, we propose to adopt the FY 2020 Hospital VBP Program measure set, for which payment begins on October 1, 2019. The performance period for these measures varies but performance ends in 2018 for all measures.

We also propose at § 414.1380(e)(1)(ii) that, starting with the 2021 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period. Therefore, for the 2021 MIPS payment year, the Total Performance Score methodology for 2019 would apply for facility-based scoring. We note that this approach of adopting all the measures in the Hospital VBP program can be applied to other VBP programs in the future, should we decide to expand facility-based measurement to settings other than hospitals in the future.

In the CY 2018 Quality Payment Program final rule we also established at

§ 414.1380(e)(6)(i) that the available quality and cost measures for facility-based measurement are those adopted under the VBP program of the facility for the year specified. We established at § 414.1380(e)(6)(ii) that we will use the benchmarks adopted under the VBP program of the facility program for the year specified (82 FR 53763 through 53764). We noted that we would determine the particular VBP program to be used for facility-based measurement in future rulemaking but would routinely use the benchmarks associated with that program (82 FR 53764). Likewise, at § 414.1380(e)(6)(iii), we established that the performance period for facility-based measurement is the performance period for the measures adopted under the VBP program of the facility program for the year specified (82 FR 53755). We noted that these provisions referred to the general parameters of our method of facility-based measurement and that we would address specific programs and years in future rulemaking (82 FR 53763). We now propose regulation for these three provisions to specify that the measures, performance period, and benchmark period for facility-based measurement are the measures, performance period, and benchmark period established for the VBP program used to determine the score as described in § 414.1380(e)(1). As an example, for the 2019 MIPS performance period and 2021 MIPS payment year, the measures used would be those for the FY 2019 Hospital VBP program along with the associated benchmarks and performance periods.

(C) Measures for MIPS 2019 Performance Period/2021 MIPS Payment Year

For informational purposes, we are providing a list of measures included in the FY 2020 Hospital VBP Program measures in determining the quality and cost performance category scores for the 2019 MIPS performance period/2021 MIPS payment year. The FY 2020 Hospital VBP Program has adopted 12 measures covering 4 domains (83 FR 20412 through 13). The performance period for measures in the Hospital VBP Program varies depending on the measure, and some measures include multi-year performance periods. We include the FY 2020 Hospital VBP Program measures in Table 49. We note that these measures are determined through separate rulemaking (82 FR 38244). As noted in section III.H.3.i.(1)(d)(v) of this proposed rule, we would adopt these measures, benchmarks, and performance periods for the purposes of facility-based measurement.

TABLE 49—FY 2020 HOSPITAL VBP PROGRAM MEASURES

Short name	Domain/measure name	NQF No.	Performance period
Person and Community Engagement Domain			
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)	January 1, 2018–December 31, 2018.
Clinical Outcomes Domain *			
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230	July 1, 2015–June 30, 2018.
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229	July 1, 2015–June 30, 2018.
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468	July 1, 2015–June 30, 2018.
THA/TKA	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550	July 1, 2015–June 30, 2018.
Safety Domain **			
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138	January 1, 2018–December 31, 2018.
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139	January 1, 2018–December 31, 2018.
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753	January 1, 2018–December 31, 2018.
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia Outcome Measure.	1716	January 1, 2018–December 31, 2018.
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure.	1717	January 1, 2018–December 31, 2018.
PC–01	Elective Delivery	0469	January 1, 2018–December 31, 2018.
Efficiency and Cost Reduction Domain			
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB).	2158	January 1, 2018–December 31, 2018.

(vi) Scoring Facility-Based Measurement

(A) Scoring Achievement in Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule, we adopted certain scoring policies for clinicians and groups in facility-based measurement. We established at § 414.1380(e)(6)(iv) and (v) that the quality and cost performance category percent scores would be established by determining the percentile performance of the facility in the VBP purchasing program for the specified year, then awarding scores associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not scored using facility-based measurement for the MIPS payment year (82 FR 53764). We also finalized at § 414.1380(e)(6)(v)(A) that clinicians scored under facility-based

measurement would not be scored on other cost measures (82 FR 53767).

For detailed descriptions of the current policies related to scoring achievement in facility-based measurement, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53763). Because we propose in section III.H.3.i.(1)(d)(iv) of this rule to not require or allow an opt-in process for facility-based measurement, we propose a change to the determination of the quality and cost performance category scores. We propose that the quality and cost performance category percent scores would be established by determining the percentile performance of the facility in the Hospital VBP Program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based

measurement for the MIPS payment year. This proposed change allows for the determination of percentile performance independent of those clinicians who would not have their quality or cost scores determined until we made the determination of their status under facility-based measurement.

(B) Scoring Improvement in Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule, we finalized that we would not give a clinician or group participating in facility-based measurement the opportunity to earn improvement points based on prior performance in the MIPS quality and cost performance categories; we noted that the Hospital VBP Program already takes improvement into account in determining the score (82 FR 53764 through 53765). We propose to add this

previously finalized policy to regulatory text at § 414.1380(e)(6)(iv) and (v).

However, we did not address a policy for a clinician or group who participates in facility-based measurement for one performance period, and then does not participate in facility-based measurement in a subsequent performance period (for example, a clinician who is scored using facility-based measurement in the 2019 MIPS performance period and is not eligible for facility-based measurement in the 2020 MIPS performance period).

After further considering the issue, we do not believe it is possible to assess improvement in the quality performance category for those who are measured under facility-based measurement in 1 year and then through another method in the following year. Our method of assessing and rewarding improvement in the MIPS quality performance category separates points awarded for measure performance from those received for bonus points (82 FR 53745). Our method of determining the quality performance category score using facility-based measurement does not allow for the separation of achievement from bonus points. For this reason, we propose at § 414.1380(b)(1)(xi)(A)(4) to not assess improvement for MIPS-eligible clinicians who are scored in MIPS through facility-based measurement in 1 year but through another method in the following year.

(vii) Expansion of Facility-Based Measurement To Use in Other Settings

We initiated the process of facility-based measurement focusing on the inpatient hospital setting but noted that we wished to consider opportunities to expand the concept into other facilities and programs and future years (82 FR 53754). We are particularly interested in the opportunity to expand facility-based measurement into post-acute care (PAC) and the end-stage renal disease (ESRD) settings and seek comment on how we may do so.

PAC is a significant sector in the spectrum of healthcare services, providing services to over 6.9 million Medicare beneficiaries annually through Long-Term Care Hospitals (LTCHs), Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), Home Health Agencies (HHAs), and Hospice.³⁰ Recent legislative efforts have focused on improving patient outcomes for PAC through the use of standardized patient assessment data to

enable information sharing and cross-setting quality assessment intended to improve outcomes in specified clinical domains. For example, section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, Pub. L. 113–185 enacted on October 6, 2014) added a new section 1899B to the Act, which requires, among other things, that LTCHs, IRFs, SNFs, and HHAs submit standardized patient assessment data on the quality measures specified under section 1899B(c) of the Act. These cross-setting quality measures, which must be calculated, at least in part, using these standardized patient assessment data, allow for the comparability of patient outcomes across PAC settings. Section 1899B(i) of the Act requires the Secretary to promulgate regulations and interpretive guidelines applicable to LTCHs, HHAs, SNFs and IRFs, hospitals and critical access hospitals that require those providers to take into account data on measures submitted by LTCHs, HHAs, SNFs and IRFs in the discharge planning process.

In response to previous rulemakings, commenters have requested the opportunity for clinicians who furnish care in PAC settings and bill Medicare Part B to be measured similarly to hospital-based clinicians. Commenters suggested that this would limit administrative burden on clinicians by avoiding clinician reporting of measures which may be similar or duplicative to those already reported for facility-based programs such as QRPs for certain PAC settings (82 FR 53754).

In light of the importance of PAC services, PAC legislative changes, and the interest of the stakeholder community, we wish to explore the opportunity to further align quality and cost measurement from the PAC QRPs with the clinicians who provide care in those settings. We need to consider alternative ways in which we may use measures from the PAC QRPs to measure clinicians in MIPS through facility-based measurement.

Therefore, we are seeking comment on how we may attribute the quality and cost of care for patients in PAC settings to clinicians. For the facility-based measurement for MIPS program, clinicians receive a score that is based on the VBP score of a particular hospital at which the clinician or group provides services to patients. We specifically solicit comment on whether a similar approach could work for PAC given the number and variation of PAC settings and clinicians. We are particularly interested to learn what level of influence MIPS-eligible clinicians have in determining performance on quality

measures for individual settings and programs in the PAC setting.

In addition, we invite comments on which PAC QRP measures may be best utilized to measure clinician performance. Under our current approach for facility-based measurement (that is, the regulations finalized previously and the proposals in this rule), all measures in the Hospital VBP Program are used to determine the MIPS score. The measures used in determining the VBP score reflect the breadth of performance in the hospital program and as such would reflect the quality of care provided by a clinician.

We also request comments on methods to identify the appropriate measures for scoring, and what measures would be most influenced by clinicians. Specifically, we solicit comment on whether all measures that are reported as part of the PAC QRPs should be included or whether we should identify a subset of measures. The 2020 LTCH QRP includes 19 measures, of which 3 are proposed to be removed as explained in the FY 2019 IPPS/LTCH proposed rule (83 FR 20512 through 20515). The 2020 IRF QRP includes 18 measures, of which 1 is proposed for removal beginning FY 2020 and 1 is proposed for removal beginning FY 2021, as explained in the FY 2019 IRF proposed rule (83 FR 21001 through 21002). The measures adopted for the 2020 SNF QRP can be found at 82 FR 36570 through 36594, and none are currently proposed for removal. The measures adopted for the 2020 HH QRP can be found at 82 FR 51717 through 51730. The measures used in the FY 2019 Hospice program can be found at 82 FR 36655 through 36656; no measures have been proposed for removal for FY 2020 in the FY 2019 Hospice Wage Index proposed rule (83 FR 20956 through 20957).

Finally, considering the attribution challenges of using measures reported by a facility to measure clinicians, we solicit comment on whether we should limit facility-based measurement to specific PAC settings and programs such as the IRF QRP or LTCH QRP, or whether we should consider all PAC settings in the facility-based measurement discussion.

In addition to our consideration of PAC settings, we also solicit comment on opportunities to consider facility-based measurement for patients with ESRD. Dialysis facilities treat patients with ESRD and acute kidney injury. The ESRD Quality Incentive Program (QIP) was the first VBP program that tied Medicare payment to a facility's performance on quality measures, and

³⁰ MedPAC. Report to the Congress: Medicare Payment Policy. 2018, Report to the Congress: Medicare Payment Policy, www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0.

payment reductions under that program began with renal dialysis services furnished on or after January 1, 2012. Like the Hospital VBP program and MIPS, this program determines scores and rewards performance based on a set of measures. However, this program only allows ESRD facilities that meet a certain threshold to avoid a negative payment adjustment and does not allow for a positive payment adjustment. We generally believe the scoring methodology associated with the ESRD QIP could be integrated into our current approach but recognize that the structure is different from the Hospital VBP Program. The Payment Year 2020 ESRD QIP measures along with a description of our scoring methodology for that payment year can be reviewed at 81 FR 77896 through 77931 and 82 FR 50760 through 50767.

Additionally, we believe MIPS eligible clinicians' roles in dialysis centers differ from their roles in hospitals. However, we believe that these clinicians have a significant impact on the quality of care for patients, even if they cannot control all aspects of their care. We seek comment on the extent to which the quality measures of dialysis centers reflect clinician performance. Additionally, we seek comments on whether we might be able to attribute the performance of a specific facility to an individual clinician. We reviewed the attribution methodology utilized for the Comprehensive ESRD Care (CEC) Model. CMS currently uses the "first touch" approach—where the beneficiary's first visit to a CEC Model participating dialysis center will prospectively match the beneficiary to the dialysis facility. While this approach ties a patient to an ESRD facility, it does not tie a clinician to an ESRD facility. We also seek comment on whether another approach, similar to our consideration of the PAC measures, might be more appropriate in this setting.

(e) Scoring the Improvement Activities Performance Category

For our previously established policies regarding scoring the improvement activities performance category, we refer readers to § 414.1380(b)(3) and the CY 2018 Quality Payment Program final rule (82 FR 53767 through 53769). We also refer readers to § 414.1355 and the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53662) and CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) for previously established policies regarding the

improvement activities performance category generally.

(i) Regulatory Text Updates

In this proposed rule, we are proposing updates to both §§ 414.1380(b)(3) and 414.1355 to more clearly and concisely capture previously established policies. We are also proposing one substantive change with respect to Patient Centered Medical Homes and comparable specialty practices. These are discussed in more detail below.

(A) Improvement Activities Performance Category Score and Total Required Points

In an effort to more clearly and concisely capture previously established policies, we are proposing updates to § 414.1380(b)(3) and refer readers to section VIII for more details.

We also are clarifying here that the improvement activities performance category score cannot exceed 100 percent.

(B) Weighting of Improvement Activities

In an effort to more clearly and concisely capture previously established policies, we are proposing updates to § 414.1380(b)(3) and refer readers to section VIII for more details.

(C) APM Improvement Activities Performance Category Score

In an effort to more clearly and concisely capture previously established policies, we are proposing updates to § 414.1380(b)(3)(i) and refer readers to section VIII for more details.

(D) Patient-Centered Medical Homes and Comparable Specialty Practices

In this proposed rule, we are proposing to modify our regulations at § 414.1380(b)(3)(ii) to more clearly and concisely capture our previously established policies for patient-centered medical homes and comparable specialty practices and refer readers to section VIII for more details.

In addition, it has come to our attention that in the preamble of the CY 2017 Quality Payment Program final rule (81 FR 77186 and 77179), the terminology "automatic" was used in reference to patient-centered medical home or comparable specialty practice improvement activities scoring credit. In that rule, in response to one comment, we stated, ". . . any MIPS eligible clinician or group that does not qualify by October 1st of the performance year as a certified patient-centered medical home or comparable specialty practice cannot receive automatic credit as such for the improvement activities

performance category." (81 FR 77186). In response to another comment in that rule, we stated, "Other certifications that are not for patient-centered medical homes or comparable specialty practices would also not qualify automatically for the highest score." (81 FR 77179).

While we used the term "automatic" then, we have since come to believe it is inaccurate because an eligible clinician or group must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive full credit for the improvement activities performance category. In the CY 2018 Quality Performance Payment final rule (82 FR 53649) in response to comments we received regarding patient-centered medical homes or comparable specialty practices receiving full credit for the improvement activities performance category for MIPS; we stated that we would like to make clear that credit is not automatically granted; MIPS eligible clinicians and groups must attest in order to receive the credit.

Therefore, in this proposed rule, we are codifying at § 414.1380(b)(3)(ii) to require that an eligible clinician or group must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive this credit. Specifically, MIPS eligible clinicians who wish to claim this status for purposes of receiving full credit in the improvement activities performance category must attest to their status as a patient-centered medical home or comparable specialty practice for a continuous 90-day minimum during the performance period.

(E) Improvement Activities Performance Category Weighting for Final Scoring

In this proposed rule, in an effort to more clearly and concisely capture previously established policies, we are proposing to make technical changes to § 414.1355(b) to state that unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the improvement activities performance category comprises 15 percent of a MIPS eligible clinician's final score for the 2019 MIPS payment year and for each MIPS payment year thereafter. We believe these changes would better align the regulation text with the text of the statute.

(ii) CEHRT Bonus

In the CY 2017 Quality Payment Program final rule (81 FR 77202 through 77209) and the CY 2018 Quality Payment Program final rule (82 FR 53664 through 53670), we established

that certain activities in the improvement activities performance category will qualify for a bonus under the Promoting Interoperability performance category if they are completed using CEHRT. This bonus is applied under the Promoting Interoperability performance category and not under the improvement activities performance category. In section III.H.3.h.(5) of this proposed rule, we are proposing a new approach for scoring the Promoting Interoperability performance category that is aligned with our MIPS program goals of flexibility and simplicity. We refer readers to section III.H.3.h.(5)(g) of this proposed rule for more details on this proposal.

We invite public comment on these proposals.

(f) Scoring the Promoting Interoperability Performance Category

We refer readers to section III.H.3.h.(5) of this proposed rule, where we discuss our proposals for scoring the Promoting Interoperability performance category.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for MIPS eligible clinicians, we refer readers to § 414.1380(c), the discussion in the CY 2017 Quality Payment Program final rule (81 FR 77319 through 77329), and the discussion in the CY 2018 Quality Payment Program final rule (82 FR 53769 through 53785). In this proposed rule, we propose to continue the complex patient bonus for the 2021 MIPS payment year, propose a modification to the final score calculation for the 2021 MIPS payment year, and propose refinements to reweighting policies.

(a) Accounting for Risk Factors

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our scoring methodology. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on individuals' health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted under section 2(d) of the Improving Medicare Post-Acute Care

Transformation Act of 2014 (IMPACT Act) and, as appropriate, other information, including information collected before completion of such studies and recommendations.

In this section, we summarize our efforts related to social risk and the relevant studies conducted under section 2(d) of the IMPACT Act. We also propose to adjust the final score by continuing a bonus to address patient complexity for the 2021 MIPS payment year.

(i) Considerations for Social Risk

In the CY 2018 Quality Payment Program final rule (82 FR 53770), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes, and how some of this disparity is related to the quality of health care.³¹ Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in our value-based purchasing programs.³² As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428 through 38429), ASPE's Report to Congress, found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as noted in the FY 2018 IPPS/LTCH PPS

final rule (82 FR 38428), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.³³ The trial period ended in April 2017 and a final report is available at http://www.qualityforum.org/SES_Trial_Period.aspx. The trial concluded that "measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship" between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,³⁴ allowing further examination of social risk factors in outcome measures.

In the CY 2018 Quality Payment Program proposed rule, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups seen by a MIPS eligible clinician that would also allow for a comparison of those differences, or disparities, across MIPS eligible clinicians (82 FR 30134). We received feedback encouraging CMS to explore whether additional factors should be used to stratify or risk adjust the individual quality and cost measures and to consider any additional factors that might be appropriate. We intend to explore options for adjustment of individual quality measures used in MIPS in future years. We also intend to explore additional approaches to account for patient risk factors through adjustments to the performance category scores or the final score. However, as described in section III.H.3.i.(2)(a)(ii), we believe it is appropriate to maintain the complex patient bonus for the 2021 MIPS payment year.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

(ii) Complex Patient Bonus for the 2021 MIPS Payment Year

In the CY 2018 Quality Payment Program final rule, under the authority in section 1848(q)(1)(G) of the Act, we

³¹ See, for example, United States Department of Health and Human Services. "Healthy People 2020: Disparities. 2014." <http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities> or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

³² Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), "Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs." December 2016. Available at <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

³³ Available at http://www.qualityforum.org/SES_Trial_Period.aspx.

³⁴ Available at <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357>.

finalized at § 414.1380(c)(3) a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year (82 FR 53771 through 53776). We intended for this bonus to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while we continue to work with stakeholders on methods to account for patient risk factors. Our overall goal for the complex patient bonus was two-fold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. We noted that we would assess on an annual basis whether to continue the bonus and how the bonus should be structured (82 FR 53771). For a detailed description of the complex patient bonus finalized for the 2020 MIPS payment year, please refer to the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776).

For the 2019 MIPS performance period/2021 MIPS payment year, we propose to continue the complex patient bonus as finalized for the 2018 MIPS performance period/2020 MIPS payment year and to revise § 414.1380(c)(3) to reflect this policy. Although we intend to maintain the complex patient bonus as a short-term solution, we do not believe we have sufficient information available at this time to develop a long-term solution to account for patient risk factors in MIPS such that we would be able to include a different approach in this proposed rule. An updated ASPE report is expected in October 2019 which will build on the analyses included in the initial reports and may provide additional input for a long-term solution to addressing risk factors in MIPS. At this time, we do not believe additional data sources are available that would be feasible to use as the basis for a different approach to account for patient risk factors in MIPS. We intend to analyze data when feasible from the 2017 MIPS

performance period which will be available following the data submission deadline on March 31, 2018 to identify differences in performance that are consistent across performance categories and may, in the future, shift the complex patient bonus to specific performance categories. However, in the absence of data analysis from the first year of MIPS, we do not believe that this change is appropriate at this time. Therefore, while we work with stakeholders to identify a long-term approach to account for patient risk factors in MIPS, we believe it would be appropriate to continue the complex patient bonus for another year to support MIPS eligible clinicians who treat patients with risk factors, as well as to maintain consistency with the 2020 MIPS payment year and minimize confusion. We have received significant feedback from MIPS eligible clinicians that consistency in the MIPS program over time is valued when possible in order to minimize confusion and to help MIPS eligible clinicians predict how they will be scored under MIPS.

Therefore, we believe it is appropriate to maintain consistent policies for the complex patient bonus in the 2021 MIPS payment year until we have sufficient evidence and new data sources that support an updated approach to account for patient risk factors.

Although we are not proposing changes to the complex patient bonus for the 2021 MIPS payment year, the dates used in the calculation of the complex patient bonus may change as a result of other proposals we are making in this proposed rule. For the 2020 MIPS payment year, we finalized that we would use the second 12-month segment of the eligibility determination period to calculate average HCC risk scores and the proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians (82 FR 53771 through 53772). As discussed in section III.H.3.a. of this proposed rule, we are proposing to change the dates of the eligibility determination period (now referred to as

the MIPS determination period) beginning with the 2021 MIPS payment year. Specifically, the second 12-month segment would begin on October 1 of the calendar year preceding the applicable performance period and end on September 30 of the calendar year in which the applicable performance period occurs. If this proposed change to the MIPS determination period is finalized, then beginning with the 2021 MIPS payment year, the second 12-month segment of the MIPS determination period (beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs) would be used when calculating average HCC risk scores and proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians.

(b) Final Score Performance Category Weights

(i) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: In general, 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category (formerly the advancing care information performance category); and 15 percent for the improvement activities performance category. For more of the statutory background and descriptions of our current policies, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77320 and 82 FR 53779, respectively). Under the proposals we are making in sections III.H.3.h.(3)(a) and III.H.3.h.(2)(a) of this proposed rule, for the 2021 MIPS payment year, the cost performance category would make up 15 percent and the quality performance category would make up 45 percent of a MIPS eligible clinician's final score. Table 50 summarizes the weights specified for each performance category.

TABLE 50—FINALIZED AND PROPOSED WEIGHTS BY MIPS PERFORMANCE CATEGORY AND MIPS PAYMENT YEAR

Performance category	Transition year (previously finalized) (percent)	2020 MIPS payment year (previously finalized) (percent)	2021 MIPS payment year (proposed) (percent)
Quality	60	50	45
Cost	0	10	15
Improvement Activities	15	15	15
Promoting Interoperability	25	25	25

(ii) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to the type of MIPS eligible clinician involved and for each measure and activity with respect to each performance category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved. Under section 1848(q)(5)(B)(i) of the Act, in the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Assigning a scoring weight of zero percent and redistributing the weight to the other performance categories differs from the scenario of a MIPS eligible clinician failing to report on an applicable measure or activity that is required to be reported.

(A) Scenarios Where the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories Would Be Reweighted

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77322 through 77325 and 82 FR 53779 through 53780, respectively), we explained our interpretation of what it means for there to be sufficient measures applicable and available for the quality and cost performance categories, and we finalized policies for the 2019 and 2020 MIPS payment years under which we would assign a scoring weight of zero percent to the quality or cost performance category and redistribute its weight to the other performance categories in the event there are not sufficient measures applicable and available, as authorized by section 1848(q)(5)(F) of the Act. For the quality performance category, we stated that having sufficient measures applicable and available means that we can calculate a quality performance category percent score for the MIPS eligible clinician because at least one quality measure is applicable and available to the clinician (82 FR 53780).

For the cost performance category, we stated that having sufficient measures applicable and available means that we can reliably calculate a score for the cost measures that adequately captures and reflects the performance of a MIPS eligible clinician (82 FR 53780). We established that if a MIPS eligible clinician is not attributed enough cases for a measure (in other words, has not met the required case minimum for the measure), or if a measure does not have a benchmark, then the measure will not be scored for that clinician (81 FR 77323). We stated that if we do not score any cost measures for a MIPS eligible clinician in accordance with this policy, then the clinician would not receive a cost performance category percent score (82 FR 53780).

We are proposing to codify these policies for the quality and cost performance categories at § 414.1380(c)(2)(i)(A)(1) and (2), respectively, and to continue them for the 2021 MIPS payment year and each subsequent MIPS payment year.

For the Promoting Interoperability performance category, in the CY 2017 Quality Payment Program final rule (81 FR 77238 through 77245) and the CY 2018 Quality Payment Program final rule (82 FR 53680 through 53687), we established policies for assigning a scoring weight of zero percent to the Promoting Interoperability performance category and redistributing its weight to the other performance categories in the final score. We are proposing to codify those policies under § 414.1380(c)(2)(i) and (iii).

For the improvement activities performance category, we continue to believe that all MIPS eligible clinicians will have sufficient activities applicable and available, except for limited extreme and uncontrollable circumstances, such as natural disasters, where a clinician is unable to report improvement activities, and circumstances where a MIPS eligible clinician joins a practice in the final 3 months of the performance period as discussed in section III.H.3.i.(2)(b)(ii)(C) of this proposed rule. Barring these circumstances, we believe that all MIPS eligible clinicians will have sufficient improvement activities applicable and available (82 FR 53780).

(B) Reweighting the Quality, Cost, and Improvement Activities Performance Categories for Extreme and Uncontrollable Circumstances

For a summary of the final policy we adopted beginning with the 2018 MIPS performance period/2020 MIPS payment year to reweight the quality, cost, and improvement activities

performance categories based on a request submitted by a MIPS eligible clinician, group, or virtual group that was subject to extreme and uncontrollable circumstances, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53780 through 53783). We are proposing to codify this policy at § 414.1380(c)(2)(i)(A)(5).

We sought comment in the CY 2018 Quality Payment Program final rule on two topics related to our extreme and uncontrollable policies (82 FR 53782 through 52783). First, in response to a public comment on the CY 2018 Quality Payment Program proposed rule in which the commenter requested that we include improvement scoring for those who are affected by extreme and uncontrollable circumstances, we sought comment on ways we could modify our improvement scoring policies to account for clinicians who have been affected by extreme and uncontrollable circumstances. In response, we received one comment expressing support for an improvement score without providing any additional details. At this time, we are not proposing modifications to our improvement scoring; therefore, MIPS eligible clinicians who receive a zero percent weighting for the quality or cost performance categories due to extreme and uncontrollable circumstances would not be eligible for improvement scoring because data sufficient to measure improvement would not be available from the performance period in which the quality or cost performance categories are weighted at zero percent.

We also sought comment on alternatives to the finalized policies, such as using a shortened performance period, which may allow us to measure performance, rather than reweighting the performance categories to zero percent. Many commenters generally supported the extreme and uncontrollable circumstances policy as finalized. One commenter requested that we reconsider our policy to not include issues third party intermediaries might have submitting information to CMS on behalf of a MIPS eligible clinician. We considered updating our policy to include third party intermediaries; however, we continue to believe that inclusion of third party intermediaries is not necessary because MIPS eligible clinicians may identify multiple ways to submit data and participate in MIPS. We seek comments on the specific circumstances under which the extreme and uncontrollable circumstances policy should be made applicable to third party intermediary issues. One

commenter recommended that CMS require MIPS eligible clinicians to submit data before an extreme and uncontrollable event and within a reasonable timeframe after the event to incentivize quality improvement while allowing for flexibility. Although we considered this alternative approach, in order to provide maximum flexibility, we continue to believe that MIPS eligible clinicians who demonstrate (through a reweighting application) that an extreme and uncontrollable event impacted their ability to report for a given performance category should have reweighting for that performance category for the performance period. However, we may consider modifying our policies in future years which we would propose through future rulemaking.

We are proposing a few minor modifications to our extreme and uncontrollable circumstances policy. First, beginning with the 2019 MIPS performance period/2021 MIPS payment year, we are proposing at § 414.1380(c)(2)(i)(A)(5) that, if a MIPS eligible clinician submits an application for reweighting based on extreme and uncontrollable circumstances, but also submits data on the measures or activities specified for the quality or improvement activities performance categories in accordance with § 414.1325, he or she would be scored on the submitted data like all other MIPS eligible clinicians, and the categories would not be reweighted. We are proposing this modification to align with a similar policy for the Promoting Interoperability performance category (82 FR 53680 through 53682). If a MIPS eligible clinician reports on measures or activities specified for the quality or improvement activities performance categories, then we assume the clinician believes there are sufficient measures or activities applicable and available to the clinician.

For most quality measures and improvement activities, the data submission occurs after the end of the MIPS performance period, so clinicians would know about the extreme and uncontrollable circumstance prior to submission. However, for the quality performance category, measures submitted via the Part B claims submission type are submitted by adding quality data codes to a claim. As a result, it is possible that a MIPS eligible clinician could have submitted some Part B claims data prior to the submission of a reweighting application for extreme and uncontrollable events. Under our proposal, we would score the quality performance category because we have received data. However, we

previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779). If a clinician experiences an extreme and uncontrollable event that affects all of the performance categories, then under our proposal the clinician would only be scored on the quality performance category if they submit data for only that category. The clinician would also have to submit data for the improvement activities or the Promoting Interoperability performance categories in order to be scored on two or more performance categories and receive a final score different than the performance threshold.

This proposal does not include administrative claims data that we receive through the claims submission process and use to calculate the cost measures and certain quality measures. As we propose to codify under § 414.1325(a)(2)(i), there are no data submission requirements for the cost performance category and for certain quality measures used to assess performance in the quality performance category. We calculate performance on these measures using administrative claims data, and clinicians are not required to submit any additional data for these measures. Therefore, we do not believe that it would be appropriate to void a reweighting application based on administrative claims data we receive for measures that do not require data submission for purposes of MIPS.

We also propose to apply the policy we finalized for virtual groups in the CY 2018 Quality Payment Program final rule (82 FR 53782 through 53783) to groups submitting reweighting applications for the quality, cost, or improvement activities performance categories based on extreme and uncontrollable circumstances. For groups, we would evaluate whether sufficient measures and activities are applicable and available to MIPS eligible clinicians in the group on a case-by-case basis and determine whether to reweight a performance category based on the information provided for the individual clinicians and practice location(s) affected by extreme and uncontrollable circumstances and the nature of those circumstances. While we did not specifically propose to apply this policy to groups in the CY 2018 Quality Payment Program proposed rule, our intention was to apply the same policy for groups and virtual groups, and thus if we adopt this proposal, we would

apply the policy to groups beginning with the 2018 performance period/2020 MIPS payment year.

(C) Reweighting the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories for MIPS Eligible Clinicians Who Join a Practice in the Final 3 Months of the Performance Period Year

Beginning with the 2019 MIPS performance period, we are proposing that a MIPS eligible clinician who joins an existing practice (existing TIN) during the final 3 months of the calendar year in which the MIPS performance period occurs (the performance period year) that is not participating in MIPS as a group would not have sufficient measures applicable and available. We are also proposing that a MIPS eligible clinician who joins a practice that is newly formed (new TIN) during the final 3 months of the performance period year would not have sufficient measures applicable and available, regardless of whether the clinicians in the practice report for purposes of MIPS as individuals or as a group. In each of these scenarios, we are proposing to reweight all four of the performance categories to zero percent for the MIPS eligible clinician and, because he or she would be scored on fewer than two performance categories, the MIPS eligible clinician would receive a final score equal to the performance threshold and a neutral MIPS payment adjustment under the policy at § 414.1380(c). We propose to codify these policies at § 414.1380(c)(2)(i)(A)(3).

We are proposing this policy because we are not currently able to identify these MIPS eligible clinicians (or groups if the group is formed in the final 3 months of the performance period year) at the start of the MIPS submission period. When we designed our systems, we incorporated user feedback that requested eligibility information be connected to the submission process. In order to submit data, an individual TIN/NPI or the group TIN must be in the files generated from the MIPS eligibility determination periods. As discussed in section III.H.3.a., we have two 12-month determination periods for eligibility. We are proposing that the second 12-month segment of the MIPS eligibility determination period would end on September 30 of the calendar year in which the applicable MIPS performance period occurs; therefore, we would have no eligibility information about clinicians who join a practice after September 30 of the performance period year. MIPS eligible clinicians who join an existing practice (existing TIN) in the

final 3 months of the performance period year that is not participating in MIPS as a group would not be identified by our systems, and we would not have the ability to inform them that they are eligible or to receive MIPS data from them. Similarly, practices that form (new TIN) in the final 3 months of the performance period year would not be in the MIPS determination files.

Accordingly, the measures and activities would not be available because any data from these MIPS eligible clinicians would not be accessible to us.

If a MIPS eligible clinician joins a practice (existing TIN) in the final 3 months of the performance period year, and the practice is not newly formed and is reporting as a group for the performance period, the MIPS eligible clinician would be able to report as part of that group. In this case, we are able to accept data for the group because the TIN would be in our MIPS eligibility determination files. Therefore, we believe the measures and activities would be available in this scenario, and reweighting would not be necessary for the MIPS eligible clinician. We note that, if a MIPS eligible clinician's TIN/NPI combination was not part of the group practice during the MIPS determination period, the TIN/NPI combination would not be identified in our system at the start of the MIPS data submission period; however, if the MIPS eligible clinician qualifies to receive the group final score under our proposal, we would apply the group final score to the MIPS eligible clinician's TIN/NPI combination as soon as the information becomes available. Please see section III.H.3.j.(1) of this proposed rule for more information about assigning group scores to MIPS eligible clinicians.

(D) Proposed Automatic Extreme and Uncontrollable Circumstances Policy Beginning With the 2020 MIPS Payment Year

In conjunction with the CY 2018 Quality Payment Program final rule, and due to the impact of Hurricanes Harvey, Irma, and Maria, we issued an interim final rule with comment period (IFC) in which we adopted on an interim final basis a policy for automatically reweighting the quality, improvement activities, and advancing care information (now referred to as Promoting Interoperability) performance categories for the transition year of MIPS (the 2017 performance period/2019 MIPS payment year) for MIPS eligible clinicians who are affected by extreme and uncontrollable circumstances affecting entire regions or locales (82 FR 53895 through 53900).

We propose to codify this policy for the quality and improvement activities performance categories at § 414.1380(c)(2)(i)(A)(6) and for the advancing care information (now Promoting Interoperability) performance category at § 414.1380(c)(2)(i)(C)(3).

We believe that a similar automatic extreme and uncontrollable circumstances policy would be appropriate for any year of the MIPS program to account for natural disasters and other extreme and uncontrollable circumstances that impact an entire region or locale. As we discussed in the interim final rule (82 FR 53897), we believe such a policy would reduce burden on clinicians who have been affected by widespread catastrophes and would align with existing policies for other Medicare programs. We propose at § 414.1380(c)(2)(i)(A)(7) and (c)(2)(i)(C)(3) to apply the automatic extreme and uncontrollable circumstances policy we adopted for the transition year to subsequent years of the MIPS program, beginning with the 2018 MIPS performance period and the 2020 MIPS payment year, with a few additions to address the cost performance category. For a description of the policy we adopted for the MIPS transition year, we refer readers to the discussion in the interim final rule (82 FR 53895 through 53900).

In the interim final rule (82 FR 53897), we stated that we were not including the cost performance category in the automatic extreme and uncontrollable circumstances policy for the transition year because the cost performance category is weighted at zero percent in the final score for the 2017 MIPS performance period/2019 MIPS payment year. We finalized a 10 percent weight for the cost performance category for the 2018 MIPS performance period/2020 MIPS payment year (82 FR 53643) and are proposing a 15 percent weight for the 2019 performance period/2021 MIPS payment year (see section III.H.3.h.(3)(a) of this proposed rule). For the reasons discussed in the CY 2018 Quality Payment Program final rule (82 FR 53781), we believe a MIPS eligible clinician's performance on measures calculated based on administrative claims data, such as the measures specified for the cost performance category, could be adversely affected by a natural disaster or other extreme and uncontrollable circumstance, and that the cost measures may not be applicable to that MIPS eligible clinician. Therefore, we are proposing to include the cost performance category in the automatic extreme and uncontrollable circumstances policy beginning with the

2018 MIPS performance period/2020 MIPS payment year. Under our policy for the transition year, if a MIPS eligible clinician in an affected area submits data for any of the MIPS performance categories by the applicable submission deadline for the 2017 MIPS performance period, he or she will be scored on each performance category for which he or she submits data, and the performance category will not be reweighted to zero percent in the final score (82 FR 53898). Our policy for the transition year did not include measures that are calculated based on administrative claims data (82 FR 53898). As discussed in the preceding section III.H.3.h.(3)(b), under § 414.1325(e), there are no data submission requirements for the cost performance category, and we will calculate performance on the measures specified for the cost performance category using administrative claims data. We are proposing for the cost performance category, if a MIPS eligible clinician is located in an affected area, we would assume the clinician does not have sufficient cost measures applicable to him or her and assign a weight of zero percent to that category in the final score, even if we receive administrative claims data that would enable us to calculate the cost measures for that clinician.

In the interim final rule (82 FR 53897), we did not include an automatic extreme and uncontrollable circumstances policy for groups or virtual groups, and we continue to believe such a policy is not necessary. Unless we receive data from a TIN indicating that the TIN would like to be scored as a group for MIPS, performance by default is assessed at the individual MIPS eligible clinician level. Similarly, performance is not assessed at the virtual group level unless the member TINs submit an application in accordance with § 414.1315. If we receive data from a group or virtual group, we would score that data, even if individual MIPS eligible clinicians within the group or virtual group are impacted by an event that would be included in our automatic extreme and uncontrollable circumstances policy. Regardless of whether we receive data from a group or virtual group, we would have no mechanism to determine whether the group or virtual group did not submit data, or submitted data and performed poorly, because it had been affected by an extreme and uncontrollable event unless the group notifies us of its circumstances. Instead of establishing a threshold for groups or virtual groups to receive automatic reweighting based on the number of

clinicians in the group or virtual group impacted by extreme and uncontrollable events, we believe it is preferable that these groups and virtual groups submit an application for reweighting based on extreme and uncontrollable circumstances under our existing policy (82 FR 53780 through 53783) where they may be eligible for reweighting if they establish that the group or virtual group was sufficiently impacted by the extreme and uncontrollable event. For example, if less than 100 percent of the clinicians in the group or virtual group were impacted, but the practice location that was responsible for data submission was among those impacted and thus impeded successful reporting for all clinicians in the group or virtual group, we believe reweighting may be appropriate.

(iii) Redistributing Performance Category Weights

In the CY 2017 and CY 2018 Quality Payment Program final rules, we established policies for redistributing the weights of performance categories for the 2019 and 2020 MIPS payment years in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories (81 FR 77325 through 77329; 82 FR 53783 through 53785, 53895 through 53900). We are proposing to codify these policies under § 414.1380(c)(2)(ii).

For the 2021 MIPS payment year, we propose at § 414.1380(c)(2)(ii)(B) to apply similar reweighting policies as finalized for the 2020 MIPS payment year (82 FR 53783 through 53785). In general, we would redistribute the weight of a performance category or categories to the quality performance category. We continue to believe redistributing weight to the quality

performance category is appropriate because of the experience MIPS eligible clinicians have had reporting on quality measures under other CMS programs. We propose to continue to redistribute the weight of the quality performance category to the improvement activities and Promoting Interoperability performance categories. However, for the 2021 MIPS payment year, with our proposal to weight cost at 15 percent, we propose to reweight the Promoting Interoperability performance category to 45 percent and the improvement activities performance category to 40 percent when the quality performance category is weighted at zero percent. We chose to weight Promoting Interoperability higher in order to align with goals of interoperability and for simplicity because we generally have avoided assigning partial percentage points to performance category weights. Reweighting scenarios under this proposal are presented in Table 51.

TABLE 51—PERFORMANCE CATEGORY REDISTRIBUTION POLICIES PROPOSED FOR THE 2021 MIPS PAYMENT YEAR

Reweighting scenario	Quality (percent)	Cost (percent)	Improvement activities (percent)	Promoting Interoperability (percent)
No Reweighting Needed:				
—Scores for all four performance categories	45	15	15	25
Reweight One Performance Category:				
—No Cost	60	0	15	25
—No Promoting Interoperability	70	15	15	0
—No Quality	0	15	40	45
—No Improvement Activities	60	15	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	15	85	0
—No Promoting Interoperability and no Improvement Activities	85	15	0	0
—No Quality and no Improvement Activities	0	15	0	85

We have heard from stakeholders in previous years that our reweighting policies place undue weight on the quality performance category, and, although we continue to believe the policies are appropriate, we seek comment on alternative redistribution policies in which we would also redistribute weight to the improvement activities performance category (see Table 52). Under the alternative redistribution policy we considered, we

would redistribute the weight of the Promoting Interoperability performance category to the quality and improvement activities performance categories. We would redistribute 15 percent of the Promoting Interoperability performance category weight to the quality performance category, and 10 percent to the improvement activities performance category. We believe redistributing more of the weight of the Promoting Interoperability performance category to

the quality performance category is appropriate because MIPS eligible clinicians have had more experience reporting on quality measures under other CMS programs than reporting on improvement activities. We would redistribute the cost performance category weight equally to the quality and improvement activities performance categories (5 percent to each) under this alternative policy.

TABLE 52—ALTERNATIVE PERFORMANCE CATEGORY REDISTRIBUTION POLICIES CONSIDERED FOR THE 2021 MIPS PAYMENT YEAR

Reweighting scenario	Alternative redistribution policy: Reweight promoting interoperability and cost to quality and improvement activities			
	Quality	Cost	Improvement activities	Promoting interoperability
No Reweighting Needed:				
—Scores for all four performance categories	45	15	15	25
Reweight One Performance Category:				
—No Promoting Interoperability	60	15	25	0
—No Cost	55	0	20	25
—No Quality	0	15	40	45
—No Improvement Activities	60	15	0	25
Reweight Two Performance Categories:				
—No Cost and No Promoting Interoperability	70	0	30	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	15	85	0
—No Promoting Interoperability and no Improvement Activities	85	15	0	0
—No Quality and no Improvement Activities	0	15	0	85

Because the cost performance category was zero percent of a MIPS eligible clinician's final score for the 2017 MIPS performance period, we did not believe it is appropriate to redistribute weight to the cost performance category for the 2019 MIPS performance period because MIPS eligible clinicians have limited experience being scored on cost measures for purposes of MIPS. In addition, we are concerned that there would be limited measures in the cost performance category under our proposal for the 2019 MIPS performance period discussed in section III.H.3.h.(3)(b) of this proposed rule, and believe it may be appropriate to delay shifting additional weight to the cost performance category until additional measures are developed. However, we also believe that cost is a critical component of the Quality Payment Program and believe placing additional emphasis on the cost performance category in future years may be appropriate. Therefore, we seek comment on redistributing weight to the cost performance category in future years.

(c) Final Score Calculation

We are proposing to revise the formula at § 414.1380(c) for calculating the final score. As discussed in section III.H.3.i.(1)(b)(vii), we are not proposing to continue to add the small practice bonus to the final score for the 2021 MIPS payment year and are proposing to add a small practice bonus to the quality performance category score instead starting with the 2021 MIPS payment year. Therefore, we are proposing to revise the formula to omit

the small practice bonus from the final score calculation beginning with the 2021 MIPS payment year. We request public comments on this proposal.

In the CY 2018 Quality Payment Program final rule (82 FR 53779), we requested public comment on approaches to display scores and provide feedback to MIPS eligible clinicians in a way that MIPS eligible clinicians can easily understand how their scores are calculated, including how performance category scores are translated to a final score. We also sought comment on how to simplify the scoring system while still recognizing differences in clinician practices.

A few commenters suggested that we make performance category scores equal to the number of points they will represent in the final score to minimize confusion. For example, the quality performance category score would be out of 50 total possible points, when the quality performance category weight is 50 percent. A few commenters provided suggestions for tools that may help MIPS eligible clinicians to understand scoring better. For example, a few commenters suggested that we create an interactive online tool for clinicians to calculate their own scores. A few commenters suggested that we should not compare MIPS eligible clinicians to benchmarks because they do not believe the benchmarks actually represent high quality care. One commenter suggested that we could simplify scoring by awarding points for multiple performance categories for performance on one measure or activity. Another commenter requested that we simplify scoring because the commenter believes that clinicians may view the program as

unfair and be subject to negative payment adjustments due to confusion rather than performance.

We thank the commenters for their suggestions, and we will take them into consideration in future rulemaking.

In response to commenters requesting that the total number of points available for a performance category should be equivalent to the performance category's weight in the final score, we note that various reweighting scenarios could mean that the weight of the performance categories for each MIPS eligible clinician may vary (for example, if the weight of one or more performance categories is redistributed to other performance categories), which makes it impossible for all MIPS eligible clinicians to have the same total number of points available for a performance category. In addition, the total points possible for the quality and cost performance categories may vary—for example, if a group is scored on the readmission measure they will have a maximum of 70 points for the 6 measures they are required to submit and the readmission measure instead of 60 points for 6 measures for individuals and groups who are not scored via Web Interface and who do not have the readmission measure. However, we continue to value simplicity in our scoring for MIPS and intend to explore approaches to simplify our scoring whenever possible in future years. We seek comments on approaches to simplify calculation of the final score that take into consideration these limitations described above.

j. MIPS Payment Adjustments

(1) Final Score Used in Payment Adjustment Calculation

For our previously established policies regarding the final score used in payment adjustment calculation, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77330 through 77332) and the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787). Under our policies, for groups submitting data using the TIN identifier, we will apply the group final score to all the TIN/NPI combinations that bill under that TIN during the performance period (82 FR 53785). We are proposing to modify this policy for the application of the group final score, beginning with the 2019 performance period/2021 MIPS payment year. We are proposing a 15-month window that starts with the second 12-month determination period (October 1 prior to the MIPS performance period through September of the MIPS performance period) and also includes the final 3 months of the performance period year (October 1 through December 31 of the performance period year). We are proposing for groups submitting data using the TIN identifier, we would apply the group final score to all of the TIN/NPI combinations that bill under that TIN during the proposed 15-month window. We believe that partially aligning with the second 12-month determination period creates consistency with our eligibility policies that informs a group or eligible clinician of who is eligible. We refer readers to section III.H.3.b. of this proposed rule where we discuss our proposals related to MIPS determination periods.

We note that, if a MIPS eligible clinician's TIN/NPI combination was not part of the group practice during the MIPS determination period, the TIN/NPI combination would not be identified in our system at the start of the MIPS data submission period; however, if the MIPS eligible clinician qualifies to receive the group final score under our proposal, we would apply the group final score to the MIPS eligible clinician's TIN/NPI combination as soon as the information becomes available.

(2) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a

year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act included a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies.

To determine a performance threshold to propose for the third year of MIPS (2021 MIPS payment year), we again relied upon the special rule in section 1848(q)(6)(D)(iii) of the Act, as amended by 51003(a)(1)(D) of the Bipartisan Budget Act of 2018. As required by section 1848(q)(6)(D)(iii) of the Act, we considered data available from a prior period with respect to performance on measures and activities that may be used under the MIPS performance categories. In accordance with newly

added clause (iv) of section 1848(q)(6)(D) of the Act, we also considered which data could be used to estimate the performance threshold for the 2024 MIPS payment year to ensure a gradual and incremental transition from the performance threshold we would establish for the 2021 MIPS payment year. We considered using the final scores for the 2017 MIPS performance period/2019 MIPS payment year; however, the data used to calculate the final scores was submitted through the first quarter of 2018, and final scores for MIPS eligible clinicians were not available in time for us to use in our analyses for purposes of this proposed rule. If technically feasible, we would consider using the actual data used to determine the final scores for the 2019 MIPS payment year to estimate a performance threshold for the 2024 MIPS payment year in the final rule.

Because the final scores for MIPS eligible clinicians are not yet available to us, we reviewed the data relied upon for the CY 2017 Quality Payment Program final rule regulatory impact analysis (81 FR 77514 through 77536) and believe it is the best data currently available to us to estimate the actual data for the 2017 MIPS performance period/2019 MIPS payment year.

Specifically, we used data from claims, MIPS eligibility data, 2015 PQRS data, 2014 PQRS Experience Report, 2014 VM data, National Plan and Provider Enumeration System Data, APM participation lists, and initial analyses for QP determination to model the estimated MIPS eligible clinicians, final scores, and the economic impact of MIPS final score. In these models, we assumed that historic PQRS participation assumptions would significantly overestimate the impact on clinicians, particularly on clinicians in practices with 1 to 15 clinicians, which have traditionally had lower participation rates. To assess the sensitivity of the impact to the participation rate, we prepared two sets of analyses. The first analysis relies on the assumption that a minimum 90 percent of MIPS eligible clinicians will participate in submitting quality performance category data to MIPS, regardless of practice size. The second analysis relies on the assumption that a minimum 80 percent of MIPS eligible clinicians will participate in submitting quality performance category data to MIPS, regardless of practice size (81 FR 77522 through 77523). We also reviewed the available data based on actual participation in PQRS (81 FR 77522 through 77523) without applying any participation assumptions.

In accordance with section 1848(q)(6)(D)(i) of the Act, the performance threshold for the 2024 MIPS payment year would be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. When we analyzed the estimated final scores for the 2019 MIPS payment year, the mean final score was between 63.50 and 68.98 points and the median was between 77.83 and 82.5 points based on the different participation assumptions. For purposes of estimating the performance threshold for the 2024 MIPS payment year, we are using the mean final score based on data used for the CY 2017 Quality Payment Program final rule regulatory impact analysis (81 FR 77514 through 77536), which would result in an estimated performance threshold between 63.50 and 68.98 points for the 2024 MIPS payment year. We note that this is only an estimation we are providing in accordance with section 1848(q)(6)(D)(iv) of the Act, and we will propose the actual performance threshold for the 2024 MIPS payment year in future rulemaking.

We propose a performance threshold of 30 points for the 2021 MIPS payment year to be codified at § 414.1405(b)(6). A performance threshold of 30 points would be a modest increase over the performance threshold for the 2020 MIPS payment year (15 points), and we believe it would provide a gradual and incremental transition to the performance threshold we would establish for the 2024 MIPS payment year, which we have estimated would be between 63.50 and 68.98 points.

We want to encourage continued participation and the collection of meaningful data by MIPS eligible clinicians. A higher performance threshold would help MIPS eligible clinicians strive to achieve more complete reporting and better performance and prepare MIPS eligible clinicians for the 2024 MIPS payment year. However, a performance threshold set too high could also create a performance barrier, particularly for MIPS eligible clinicians who did not previously participate in PQRS or the EHR Incentive Programs. Additionally, we believe a modest increase from the performance threshold for the 2020 MIPS payment year would be particularly important to reduce the burden for MIPS eligible clinicians in small or solo practices. We believe that active participation of MIPS eligible clinicians in MIPS will improve the overall quality, cost, and care coordination of services provided to Medicare beneficiaries.

We have heard from stakeholders requesting that we continue a low performance threshold and from stakeholders requesting that we ramp up the performance threshold to help MIPS eligible clinicians prepare for a future performance threshold of the mean or median of final scores and to meaningfully incentivize higher performance. We have also heard from stakeholders who believe a higher performance threshold may incentivize higher performance by MIPS eligible clinicians through higher positive MIPS payment adjustments for those who exceed the performance threshold. We believe that a performance threshold of 30 points for the 2021 MIPS payment year would provide a gradual and incremental increase from the performance threshold of 15 points for the 2020 MIPS payment year and could incentivize higher performance by MIPS eligible clinicians.

We also believe that a performance threshold of 30 points represents a meaningful increase compared to 15 points, while maintaining flexibility for MIPS eligible clinicians in the pathways available to achieve this performance threshold. For example, generally a MIPS eligible clinician that is reporting individually and is not in a small practice could meet the performance threshold of 30 points by earning 40 measure achievement points out of 60 total possible measure achievement points that could be achieved through performing at the highest level of performance for 2 measures and earning 5 measure achievement points for each of the 4 other measures submitted for a total of 6 required measures submitted in the quality performance category (assuming an outcome measure is submitted).³⁵ Alternatively, a performance threshold of 30 points could be met by performance at 50 percent for the Promoting Interoperability performance category (receiving a 50 percent performance category score with a performance category weight of 25 percent of the final score is 12.5 points), receiving a 50 percent performance category score for the cost performance category (receiving a 50 percent performance category score with a performance category weight of 15 percent of the final score is 7.5

³⁵ The score for the quality performance category would be (10 measure achievement points × 2 measures plus 5 measure achievement points × 4 measures)/60 total possible achievement points or 66.67 percent. That score could be higher if the clinician qualifies for bonuses in the quality performance category. The 66.67 percent quality performance category percent score is weighted at 45 percent of the final score which is multiplied by 100 and equals 30 points towards the final score.

points), and also earning the maximum number of points for the improvement activities performance category (which is worth 15 points towards the final score), which collectively would produce a final score of at least 35 points (15 points for improvement activities + 7.5 points for cost + 12.5 points for Promoting Interoperability).

We refer readers to section III.H.3.j.(4)(e) of this proposed rule for additional examples of how a MIPS eligible clinician can meet or exceed the performance threshold. We invite public comment on the proposal to set the performance threshold for the 2021 MIPS payment year at 30 points. Alternatively, we considered whether the performance threshold should be set at a higher or lower number, for example, 25 points or 35 points, and also seek comment on alternative numerical values for the performance threshold for the 2021 MIPS payment year.

We also seek comment on our approach to estimating the performance threshold for the 2024 MIPS payment year, which above we based on the estimated mean final score for the 2019 MIPS payment year. We are particularly interested in whether we should use the median, instead of the mean, and whether in the future we should estimate the mean or median based on the final scores for another MIPS payment year. In our model estimates, we have seen that the mean scores are lower than the median and would expect a larger proportion of clinicians estimated to have final scores above the mean, rather than the median, because the mean is lower than the median with those who do not submit the required data getting the lowest possible score. That in turn could lower the scaling factor compared to a performance threshold based on the median. We also seek comment on whether establishing a path forward to a performance threshold for the 2024 MIPS payment year that provides certainty to clinicians and ensures a gradual and incremental increase from the performance threshold for the 2021 MIPS payment year to the estimated performance threshold for the 2024 MIPS payment year would be beneficial. For example, we could consider setting a performance threshold of 30 points for the 2021 MIPS payment year, 50 points for the 2022 MIPS payment year, and 70 points for the 2023 MIPS payment year as gradual and incremental increases toward the estimated performance threshold for the 2024 MIPS payment year based on our estimated median final scores discussed above; or we could have slightly lower values if we were to continue to

estimate the performance threshold for the 2024 MIPS payment year based on our estimated mean final scores. We believe there may be value to MIPS eligible clinicians in knowing in advance the performance threshold for the 2022 and 2023 MIPS payment years to encourage and facilitate increased clinician engagement and prepare clinicians for meeting the performance threshold for the 2024 MIPS payment year. Alternatively, we also believe that our estimates for the 2024 MIPS payment year performance threshold may change as we analyze actual MIPS data and, therefore, it may be appropriate to propose the performance threshold annually as we better understand the mean and median final scores.

(3) Additional Performance Threshold for Exceptional Performance

Section 1848(q)(6)(D)(ii) of the Act requires the Secretary to compute, for each year of the MIPS, an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors for exceptional performance under section 1848(q)(6)(C) of the Act. For each such year, the Secretary shall apply either of the following methods for computing the additional performance threshold: (1) The threshold shall be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold determined under section 1848(q)(6)(D)(i) of the Act; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold for the prior period described in section 1848(q)(6)(D)(i) of the Act.

Under section 1848(q)(6)(C) of the Act, a MIPS eligible clinician with a final score at or above the additional performance threshold will receive an additional MIPS payment adjustment factor and may share in the \$500,000,000 of funding available for the year under section 1848(q)(6)(F)(iv) of the Act.

As we discussed in section III.H.3.j.(2) of this proposed rule, we are relying on the special rule under section 1848(q)(6)(D)(iii) of the Act, as amended by section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018, to propose a performance threshold of 30 points for the 2021 MIPS payment year. The special rule under section 1848(q)(6)(D)(iii) of the Act also applies for purposes of establishing an additional performance threshold for a year. For the 2021 MIPS payment year, we are proposing to again decouple the

additional performance threshold from the performance threshold.

Because we do not have actual MIPS final scores for a prior performance period, if we do not decouple the additional performance threshold from the performance threshold, then we would have to set the additional performance threshold at the 25th percentile of possible final scores above the performance threshold. With a performance threshold set at 30 points, the range of total possible points above the performance threshold is 30.01 to 100 points and the 25th percentile of that range is 47.5, which is less than one-half of the possible 100 points in the MIPS final score. We do not believe it would be appropriate to lower the additional performance threshold to 47.5 points because we do not believe a final score of 47.5 points demonstrates exceptional performance by a MIPS eligible clinician. We believe these additional incentives should only be available to those clinicians with very high performance on the MIPS measures and activities. Therefore, we are relying on the special rule under section 1848(q)(6)(D)(iii) of the Act and propose at § 414.1405(d)(5) to set the additional performance threshold at 80 points for the 2021 MIPS payment year, which is higher than the 25th percentile of the range of the possible final scores above the performance threshold.

As required by section 1848(q)(6)(D)(iii) of the Act, we took into account the data available and the modeling described in section VII. of this proposed rule to estimate final scores for the 2021 MIPS payment year. We believe 80 points is appropriate because it is vital to incentivize clinicians who have made greater strides to meaningfully participate in the MIPS program to perform at even higher levels. An additional performance threshold of 80 points requires a MIPS eligible clinician to perform well on at least two performance categories. Generally, a MIPS eligible clinician could receive a maximum score of 45 points for the quality performance category, which is below the 80-point additional performance threshold. In addition, 80 points is at a high enough level that MIPS eligible clinicians must submit data for the quality performance category to achieve this target. For example, if a MIPS eligible clinician gets a perfect score for the improvement activities, the cost, and Promoting Interoperability performance categories, but does not submit quality measures data, then the MIPS eligible clinician would only receive 55 points (0 points for quality + 15 points for the cost

performance category + 15 points for improvement activities + 25 points for Promoting Interoperability performance category), which is below the additional performance threshold. We believe the additional performance threshold at 80 points increases the incentive for excellent performance while keeping the focus on quality performance.

We also believe this increase would encourage increased engagement and further incentivize clinicians whose performance meets or exceeds the additional performance threshold, recognizing that a fixed amount is available for a year under section 1848(q)(6)(F)(iv) of the Act to fund the additional MIPS payment adjustments and that the more clinicians who receive an additional MIPS payment adjustment, the lower the average clinician's additional MIPS payment adjustment will be.

For future years, we may consider additional increases to the additional performance threshold.

(4) Application of the MIPS Payment Adjustment Factors

(a) Application to the Medicare Paid Amount for Covered Professional Services

In the CY 2018 Quality Payment Program final rule, we finalized the application of the MIPS payment adjustment factor, and if applicable, the additional MIPS payment adjustment factor, to the Medicare paid amount for items and services paid under Part B and furnished by the MIPS eligible clinician during the year (82 FR 53795). Sections 51003(a)(1)(A)(i) and 51003(a)(1)(E) of the Bipartisan Budget Act of 2018 amended sections 1848(q)(1)(B) and 1848(q)(6)(E) of the Act, respectively, by replacing the references to "items and services" with "covered professional services" (as defined in section 1848(k)(3)(A) of the Act). Covered professional services as defined in section 1848(k)(3)(A) of the Act are those services for which payment is made under, or is based on, the Medicare Physician Fee Schedule and which are furnished by an eligible professional. As a result of these changes, the MIPS payment adjustment factor determined under section 1848(q)(6)(A), and as applicable, the additional MIPS payment adjustment factor determined under section 1848(q)(6)(C) of the Act, will be applied to Part B payments for covered professional services furnished by a MIPS eligible clinician during a year beginning with the 2019 MIPS payment year and not to Part B payments for other items and services.

To conform with these amendments to the statute, we are proposing to revise § 414.1405(e) to apply the MIPS payment adjustment factor and, if applicable, the additional MIPS payment adjustment factor, to the Medicare Part B paid amount for covered professional services furnished by a MIPS eligible clinician during a MIPS payment year (beginning with 2019). We are also proposing to revise § 414.1405(e) to specify the formula for applying these adjustment factors in a manner that more closely tracks the statutory formula under section 1848(q)(6)(E) of the Act. Specifically, we are proposing the following formula: In the case of covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by a MIPS eligible clinician during a MIPS payment year beginning with 2019, the amount otherwise paid under Part B with respect to such covered professional services and MIPS eligible clinician for such year, is multiplied by 1, plus the sum of: The MIPS payment adjustment factor divided by 100, and as applicable, the additional MIPS payment adjustment factor divided by 100. We also refer readers to section III.H.3.a. of this proposed rule where we discuss the covered professional services to which the MIPS payment adjustment could be applied.

(b) Application for Non-Assigned Claims for Non-Participating Clinicians

In the CY 2018 Quality Payment Program final rule, we did not address the application of the MIPS payment adjustment for non-assigned claims for non-participating clinicians. In the CY 2018 Quality Payment Program final rule, we responded to a comment requesting guidance on how the MIPS payment adjustment and the calculation of the Medicare limiting charge amount would be applied for non-participating clinicians, and we stated our intention to address these issues in future rulemaking (82 FR 53795). Beginning with the 2019 MIPS payment year, we are proposing that the MIPS payment adjustment does not apply for non-assigned claims for non-participating clinicians. This approach is consistent with the policy for application of the value modifier that was finalized in the CY 2015 Physician Fee Schedule final rule (79 FR 67950 through 67951). Sections 1848(q)(6)(A) and 1848(q)(6)(C) of the Act require that we specify a MIPS payment adjustment factor, and if applicable, an additional MIPS payment adjustment factor for each MIPS eligible clinician, and section 1848(q)(6)(E) of the Act (as amended by section 51003(a)(1)(E) of the Bipartisan Budget

Act of 2018) requires that these payment adjustment factor(s) be applied to adjust the amount otherwise paid under Part B for covered professional services furnished by the MIPS eligible clinician during the MIPS payment year. When non-participating clinicians choose not to accept assignment for a claim, Medicare makes payment directly to the beneficiary, and the physician collects payment from the beneficiary. This is referred to as a non-assigned claim. Application of the MIPS payment adjustment to these non-assigned claims would not affect payment to the MIPS eligible clinician. Rather, it would only affect Medicare payment to the beneficiary. If the MIPS payment adjustment were to be applied to non-assigned services, then the Medicare payment to a beneficiary would be increased when the MIPS payment adjustment is positive and decreased when the MIPS payment adjustment is negative. Although the statute does not directly address this situation, it does suggest that the MIPS payment adjustment is directed toward payment to the MIPS eligible clinician and the covered professional services they furnish. We continue to believe that it is important that beneficiary liability not be affected by the MIPS payment adjustment and that the MIPS payment adjustment should be applied to the amount that Medicare pays to MIPS eligible clinicians.

On that basis, we propose to apply the MIPS payment adjustment to claims that are billed and paid on an assignment-related basis, and not to any non-assigned claims, beginning with the 2019 MIPS payment year. We do not expect this proposal, that the MIPS payment adjustment would not apply to non-assigned claims, would be likely to affect a clinician's decision to participate in Medicare or to otherwise accept assignment for a particular claim, but we seek comment on whether stakeholders and others believe clinician behavior would change as a result of this policy.

(c) Waiver of the Requirement To Apply the MIPS Payment Adjustment Factors to Certain Payments in Models Tested Under Section 1115A of the Social Security Act

CMS tests models under section 1115A of the Act that may include model-specific payments made only to model participants under the terms of the model and not to any other providers of services or suppliers. Some of these model-specific payments may be considered payments for covered professional services furnished by a MIPS eligible clinician, meaning that

the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) applied under § 414.1405(e) of our regulations would normally apply to those payments. Section 1115A(d)(1) of the Act authorizes the Secretary to waive requirements of Title XVIII of the Act (and certain other requirements) as may be necessary solely for the purposes of testing models under section 1115A. We believe it is necessary to waive the requirement to apply the MIPS payment adjustment factors to a model-specific payment or payments (to the extent such a payment or payments are subject to the requirement to apply the MIPS payment adjustment factors) for purposes of testing a section 1115A model under which such model-specific payment or payments are made in a specified payment amount (for example, \$160 per-beneficiary, per-month); or paid according to a methodology for calculating a model-specific payment that is applied in a consistent manner to all model participants. In both cases, applying the MIPS payment adjustment factors to these model-specific payments would introduce variation in the amounts of model-specific payments paid across model participants, which could compromise the model test and the evaluation thereof.

We propose to amend § 414.1405 to add a new paragraph (f) to specify that the MIPS payment adjustment factors applied under § 414.1405(e) would not apply to certain model-specific payments as described above for the duration of a section 1115A model's testing, beginning in the 2019 MIPS payment year. We are proposing to use the authority under section 1115A(d)(1) of the Act to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and § 414.1405(e) specifically for these types of payments because the waiver is necessary solely for purposes of testing models that involve such payments.

We believe this policy is appropriate because it would enable us to effectively test and evaluate the payment and savings impacts of such model-specific payments made under section 1115A models during model testing, which may not be possible if the requirement to apply the MIPS payment adjustment factors was not waived. This waiver would not apply to payments made outside of a section 1115A model with respect to both MIPS eligible clinicians that are participating in and MIPS eligible clinicians that are not participating in a section 1115A model.

To illustrate how this waiver would apply, one model-specific payment to which this proposed rule would apply is the Monthly Enhanced Oncology Services (MEOS) payment in the Oncology Care Model (OCM). The duration of this waiver would begin with the 2019 MIPS payment year and continue for the duration of OCM. Application of our proposed regulation to the MEOS payment illustrates why the waiver is necessary for some payments under section 1115A models. OCM incorporates two model-specific payments for participating practices, creating incentives to improve the quality of care at a lower cost and furnish enhanced services for beneficiaries who undergo chemotherapy treatment for a cancer diagnosis. There is a per-beneficiary per-month MEOS payment for the duration of each 6-month episode of chemotherapy care attributed to the practice, and there is the potential for a performance-based payment for such episodes.

MEOS payments are for Enhanced Services furnished to the OCM practices' beneficiary population for attributed episodes of care (that is, 24/7 access, patient navigation, care planning, and using therapies consistent with nationally recognized clinical guidelines); while some beneficiaries attributed to an OCM Practice will require more support than others, all beneficiaries in episodes of care attributed to an OCM practice have access to the OCM Enhanced Services throughout their 6-month episode. The MEOS payment is set at \$160 per beneficiary per month for all OCM Practitioners. Because the MEOS payments are made for services for which payment is made under, or based on the PFS and which are furnished by an eligible clinician, they are considered covered professional services as defined in section 1848(k)(3)(A) of the Act. Accordingly, beginning in 2019 (the first MIPS payment year), the MEOS payments would be subject to the MIPS payment adjustments (positive, neutral, or negative) that are applicable for each OCM Practitioner who is a MIPS eligible clinician (at the TIN/NPI level) unless the requirement to apply the MIPS payment adjustment factors to the MEOS payments is waived pursuant to section 1115A(d)(1) of the Act.

We believe it is necessary to waive the requirement to apply the MIPS payment adjustment factors to the MEOS payments solely for purposes of testing OCM because we established the \$160 per beneficiary per month MEOS payment rate after careful study and consideration, and we are specifically

testing the impact and appropriateness of \$160 as the per beneficiary per month MEOS payment amount to OCM Practitioners. Though some payment adjustments such as sequestration apply to MEOS payments, we do not apply others that would result in differential payments across OCM Practitioners, such as the Geographic Pricing Cost Index adjustment and Value-Based Payment Modifier for CY 2018. If the MEOS payments were subject to the MIPS payment adjustment, the MEOS payment amount would not be consistent for all OCM Practitioners across the OCM. We are concerned that the resulting differential MEOS payment amounts would increase the complexity of the model evaluation. Specifically, if OCM practices receive differential MEOS payment amounts, they would therefore receive different levels of payment from OCM per attributed beneficiary, which could provide differential incentives for OCM practices to invest in care coordination and other practice transformation activities. This would substantially increase the complexity of evaluating the impact of the model, as it would be challenging to evaluate how these differential payment amounts influence outcomes, potentially lessening our ability to accurately discern whether \$160 per beneficiary per month is the appropriate payment amount. These differential payment amounts may also potentially distort CMS's intent to incentivize the provision of enhanced oncology care by OCM Practitioners via a standardized per-beneficiary per-month payment for such services.

We propose to provide the public with notice that this proposed new regulation applies to model-specific payments that the Innovation Center elects to test in the future in two ways: First, we will update the Quality Payment Program website (www.qpp.cms.gov) when new model-specific payments subject to this proposed waiver are announced, and second, we will provide a notice in the **Federal Register** to update the public on any new model-specific payments to which this waiver will apply.

(d) CY 2018 Exclusion of MIPS Eligible Clinicians Participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

In conjunction with releasing this proposed rule, CMS is announcing the MAQI Demonstration, authorized under section 402 of the Social Security Amendments of 1968 (as amended). The MAQI Demonstration is designed to test whether excluding MIPS eligible

clinicians who participate to a sufficient degree in certain payment arrangements with Medicare Advantage Organizations (MAOs) from the MIPS reporting requirements and payment adjustment will increase or maintain participation in payment arrangements similar to Advanced APMs with MAOs and change the manner in which clinicians deliver care.

If the waivers proposed below are finalized, the MAQI Demonstration will allow certain participating clinicians to be excluded from the MIPS reporting requirements and payment adjustment (if the clinicians participate to a sufficient degree in a combination of Qualifying Payment Arrangements with MAOs and Advanced APMs with Medicare FFS during the performance period for that year) without meeting the criteria to be QPs or otherwise meeting a MIPS exclusion criterion under the Quality Payment Program. For example, eligible clinicians that did not meet the criteria to be a QP for a given year, or were not otherwise eligible to be excluded from MIPS (that is, were not newly enrolled in Medicare or did not fall below the low volume threshold for Medicare FFS patients or payments) could be excluded from the MIPS reporting requirements and payment adjustment through the Demonstration. For purposes of the MAQI Demonstration, we would apply requirements for Qualifying Payment Arrangements that are consistent with the criteria for Other Payer Advanced APMs under the Quality Payment Program as set forth in § 414.1420. In addition, we are proposing that the combined thresholds for Medicare payments or patients through Qualifying Payment Arrangements with MAOs and Advanced APMs that a participating clinician must meet in order to attain waivers of the MIPS reporting requirements and payment adjustment through the MAQI Demonstration matches the thresholds for participation in Advanced APMs under the Medicare Option of the Quality Payment Program. In 2018, those thresholds are 25 percent for the payment amount threshold and 20 percent for the patient count threshold. Under the MAQI Demonstration, aggregate participation in Advanced APMs and Qualifying Payment Arrangements will be used, without applying a specific minimum threshold to participation in either type of payment arrangement.

Section 402(b) of the Social Security Amendments of 1968 (as amended) authorizes the Secretary to waive requirements of Title XVIII that relate to payment and reimbursement in order to carry out demonstrations under section

402(a). We propose to use the authority in section 402(b) of the Social Security Amendments of 1968 (as amended) to waive requirements of section 1848(q)(6)(E) of the Act and the regulations implementing it, to waive the payment consequences (positive, negative or neutral adjustments) of the MIPS and to waive the associated MIPS reporting requirements in 42 CFR part 414 adopted to implement the payment consequences, subject to conditions outlined in the Demonstration. As a practical matter, the waiver would have the effect of acting as another exclusion from MIPS for eligible clinicians who participate in the MAQI Demonstration and meet the performance thresholds set in the demonstration. To qualify for these waivers, a participating clinician must participate to a sufficient degree in Qualifying Payment Arrangements with MAOs and Advanced APMs in FFS Medicare during the performance period for that year, without meeting the criteria to be QPs or Partial QPs, or otherwise meeting the MIPS exclusion criteria of the Quality Payment Program. The threshold to qualify for the waivers using participation in these specific payment arrangements could be met in one of two ways: A certain percentage of payments or patients is tied to participation in a combination of Advanced APMs and Qualifying Payment Arrangements. These thresholds will match the thresholds under the Medicare Option of the Quality Payment Program. We propose to begin the MAQI Demonstration in Calendar 2018, with the 2018 Performance Period, and operate the project for a total of 5 years.

The Demonstration will also waive the provision in section 1848(q)(1)(A) of the Act that the Secretary shall permit any eligible clinician to report on applicable measures and activities, so that the Demonstration will prohibit reporting under the MIPS by eligible clinicians who participate in the Demonstration and meet the thresholds to receive the waivers from the MIPS reporting requirements and payment adjustment for a given year. This waiver is necessary to prevent the potential gaming opportunity wherein participating clinicians could intentionally report artificially poor performance under the MIPS for years in which they receive waivers from MIPS payment consequences, then receive artificially inflated quality improvement points under MIPS in later years when they do not receive waivers from MIPS payment consequences. We believe this waiver is necessary under the Demonstration because the

Demonstration creates a scenario in which participating clinicians could report to MIPS, not be subject to the MIPS payment adjustment for that year, but have that year's data used in the calculation of quality improvement points in future years. Clinicians who are excluded from the MIPS reporting requirements and payment adjustment through participation in the Demonstration would not be permitted to report to MIPS. Clinicians who participate in the Demonstration but are not excluded from MIPS (whether through participation in the Demonstration or otherwise) would continue to be MIPS eligible clinicians who are subject to the MIPS reporting requirements and payment adjustment as usual.

Because of the requirement to ensure budget neutrality with regard to the MIPS payment adjustments under section 1848(q)(6)(F)(ii) of the Act, removing MIPS eligible clinicians from the population across which positive and negative payment adjustments are calculated under MIPS may affect the payment adjustments for other MIPS eligible clinicians. Specifically, the Demonstration would exclude certain clinicians from the pool of MIPS eligible clinicians for which the MIPS payment adjustments are calculated, thereby decreasing the aggregate allowed charges resulting from the application of MIPS adjustment factors included in the budget neutrality determination. The application of waivers to MIPS eligible clinicians participating to a sufficient degree in the MAQI Demonstration may have the effect of changing the aggregate amount of MIPS payment adjustments received by MIPS eligible clinicians to whom the waivers do not apply. The Demonstration is contingent on the finalization of these waivers through rulemaking due to its effect on MIPS payment adjustments for other clinicians.

We invite comment on this proposal.

(e) Example of Adjustment Factors

We provide a figure and several tables as illustrative examples of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on our proposed policies for the 2021 MIPS payment year.

Figure A (below) provides an example of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on proposed policies for the 2021 MIPS payment year. In Figure A, the

performance threshold is 30 points. The applicable percentage is 7 percent for the 2021 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 7 percent for the 2021 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 7.5 points based on the performance threshold of 30 points for the 2021 MIPS payment year). All MIPS eligible clinicians with a final score in this range would receive the lowest negative applicable percentage (negative 7 percent for the 2021 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 would be less than or equal to 7 percent. If the scaling factor is above 1.0, but less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 would be higher than 7 percent.

Only those MIPS eligible clinicians with a final score equal to 30 points (which is the performance threshold in this example) would receive a neutral MIPS payment adjustment. Because the performance threshold is 30 points, we anticipate that more clinicians will receive a positive adjustment than a negative adjustment and that the scaling factor would be less than 1 and the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points would be less than 7 percent.

Figure A illustrates an example of the slope of the line for the linear adjustments and has been updated from prior rules, but it could change considerably as new information becomes available. In this example, the scaling factor for the MIPS payment adjustment factor is 0.229. In this example, MIPS eligible clinicians with a final score equal to 100 would have a MIPS payment adjustment factor of 1.60 percent (7 percent \times 0.229).

The additional performance threshold is 80 points. An additional MIPS payment adjustment factor of 0.5

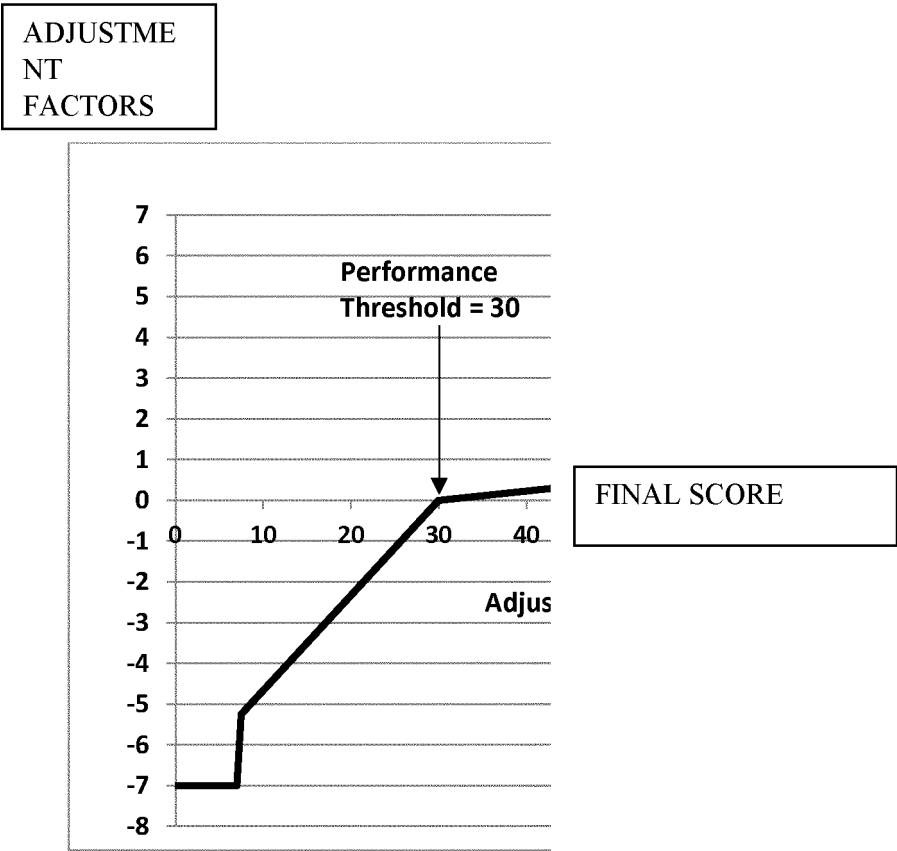
percent starts at the additional performance threshold and increases on a linear sliding scale up to 10 percent. This linear sliding scale line is also multiplied by a scaling factor that is greater than zero and less than or equal to 1.0. The scaling factor will be determined so that the estimated aggregate increase in payments

associated with the application of the additional MIPS payment adjustment factors is equal to \$500,000,000. In Figure A, the example scaling factor for the additional MIPS payment adjustment factor is 0.407. Therefore, MIPS eligible clinicians with a final score of 100 would have an additional MIPS payment adjustment factor of 4.07

percent (10 percent \times 0.407). The total adjustment for a MIPS eligible clinician with a final score equal to 100 would be $1 + 0.0106 + 0.0407 = 1.0567$, for a total positive MIPS payment adjustment of 5.67 percent.

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FIGURE A: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2021 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 7 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality, but cannot be higher than 3.0. The additional adjustment factor is also illustrative. The additional adjustment factor starts at 0.5 percent and cannot exceed 10 percent and is also multiplied by a scaling factor that is greater than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

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The final MIPS payment adjustments will be determined by the distribution of final scores across MIPS eligible clinicians and the performance threshold. More MIPS eligible clinicians

above the performance threshold means the scaling factors would decrease because more MIPS eligible clinicians receive a positive MIPS payment adjustment factor. More MIPS eligible clinicians below the performance

threshold means the scaling factors would increase because more MIPS eligible clinicians would receive a negative MIPS payment adjustment factor and relatively fewer MIPS eligible

clinicians would receive a positive MIPS payment adjustment factor.

Table 53 illustrates the changes in payment adjustments based on the final

policies from the 2019 MIPS payment year and the 2020 MIPS payment year, and on the proposed policies for the 2021 MIPS payment year, as well as the

statutorily required increase in the applicable percent as required by section 1848(q)(6)(B) of the Act.

TABLE 53—ILLUSTRATION OF POINT SYSTEM AND ASSOCIATED ADJUSTMENTS COMPARISON BETWEEN TRANSITION YEAR AND THE 2020 MIPS PAYMENT YEAR AND 2021 MIPS PAYMENT YEAR

Transition year		2020 MIPS payment year		2021 MIPS payment year	
Final score points	MIPS adjustment	Final score points	MIPS adjustment	Final score points	MIPS adjustment
0.0–0.75	Negative 4%	0.0–3.75	Negative 5%	0.0–7.5	Negative 7%.
0.76–2.99	Negative MIPS payment adjustment greater than negative 4% and less than 0% on a linear sliding scale.	3.76–14.99	Negative MIPS payment adjustment greater than negative 5% and less than 0% on a linear sliding scale.	7.51–29.99	Negative MIPS payment adjustment greater than negative 7% and less than 0% on a linear sliding scale.
3.00	0% adjustment	15.0	0% adjustment	30.0	0% adjustment.
3.01–69.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 4% for scores from 3.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	15.01–69.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for scores from 15.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	30.01–79.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for scores from 30.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.
70.0–100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 4% for scores from 3.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS. An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 70.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.	70.0–100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for scores from 15.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS. An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 70.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.	80.0–100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for scores from 30.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS. An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 80.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.

We have provided updated examples below for the 2021 MIPS payment year to demonstrate scenarios in which MIPS eligible clinicians can achieve a final score at or above the performance threshold of 30 points for the 2021 MIPS payment year.

Example 1: MIPS Eligible Clinician in Small Practice Submits 1 Quality Measure and 1 Improvement Activity

In the example illustrated in Table 54, a MIPS eligible clinician in a small practice reporting individually exceeds the performance threshold by reporting 1 quality measure via claims and performing at the highest level on the measure, for which the MIPS eligible

clinician receives 10 measure achievement points, and reporting one medium-weight improvement activity. The practice does not submit data for the Promoting Interoperability performance category but does submit a significant hardship exception application which is approved; therefore, the weight for the Promoting Interoperability performance category is

redistributed to the quality performance category under the reweighting policies discussed in this proposed rule at section III.H.3.i.(2)(b). We note that this example is only intended to illustrate that small practices may be later adopters of CEHRT and that during the transition period there are opportunities to succeed while practices work towards CEHRT adoption and interoperability. We also assumed the small practice has a cost performance category percent score of 50 percent. Finally, we assumed a complex patient bonus of 3 points. There are several special scoring rules which affect MIPS eligible clinicians in a small practice:

- 10 measure achievement points for the 1 quality measure submitted at the highest level of performance. We refer readers to this policy at § 414.1380(b)(1).

Because the measure is submitted via claims, it does not qualify for the end-to-end electronic reporting bonus, nor would it qualify for the high-priority bonus because it is the only measure submitted. Because the MIPS eligible clinician does not meet full participation requirements, the MIPS eligible clinician does not qualify for improvement scoring. However, because the clinician did submit a measure, the clinician is able to receive 3 measure bonus points for the small practice bonus. Therefore, the quality performance category is (10 measure achievement points + 3 measure bonus points)/60 total available measure points + zero improvement percent score which is 21.67 percent.

- The Promoting Interoperability performance category weight is

redistributed to the quality performance category so that the quality performance category score is worth 70 percent of the final score. We refer readers to section III.H.3.i.(2)(b) of this proposed rule for a discussion of reweighting policies.

- MIPS eligible clinicians in small practices qualify for special scoring for improvement activities so a medium weighted activity is worth 20 points (instead of 10 points for MIPS eligible clinicians generally) out of a total of 40 possible points for the improvement activities performance category. We refer readers to § 414.1380(b)(3) for this policy.

- This MIPS eligible clinician exceeds the performance threshold of 30 points (but does not exceed the additional performance threshold). This score is summarized in Table 54.

TABLE 54—SCORING EXAMPLE 1, MIPS ELIGIBLE CLINICIAN IN A SMALL PRACTICE

[A] Performance category	[B] Performance score	[C] Category weight	[D] Earned points ([B] * [C] * 100)
Quality	21.67%	70%	15.17
Cost	50%	15%	7.5
Improvement Activities	20 out of 40 points—50%	15%	7.5
Promoting Interoperability	N/A	0% (reweighted to quality)	0
Subtotal (Before Bonus)	30.17
Complex Patient Bonus	3
Final Score (not to exceed 100).	33.17

Example 2: Group Submission Not in a Small Practice

In the example illustrated in Table 55, a MIPS eligible clinician in a medium size practice participating in MIPS as a group receives performance category scores of 85 percent for the quality performance category, 50 percent for the cost performance category, 75 percent

for the Promoting Interoperability, and 100 percent for the improvement activities performance categories. There are many paths for a practice to receive an 85 percent score in the quality performance category, so for simplicity we are assuming the score has been calculated at this amount. The final score is calculated to be 82.5, and both the performance threshold of 30 and the

additional performance threshold of 80 are exceeded. Again, for simplicity, we assume a complex patient bonus of 3 points. In this example, the group practice does not qualify for any special scoring, yet is able to exceed the additional performance threshold and will receive the additional MIPS payment adjustment factor.

TABLE 55—SCORING EXAMPLE 2, MIPS ELIGIBLE CLINICIAN IN A MEDIUM PRACTICE

[A] Performance category	[B] Performance score	[C] Category weight	[D] Earned points ([B] * [C] * 100)
Quality	85%	45%	38.25
Cost	50%	15%	7.5
Improvement Activities	40 out of 40 points—100%	15%	15
Promoting Interoperability	75%	25%	18.75
Subtotal (Before Bonus)	79.5
Complex Patient Bonus	3
Final Score (not to exceed 100)	82.5

Example 3: Non-Patient Facing MIPS Eligible Clinician

In the example illustrated in Table 56, an individual MIPS eligible clinician that is non-patient facing and not in a small practice receives performance category scores of 50 percent for the quality performance category, 50 percent for the cost performance category, and 50 percent for 1 medium-weighted improvement activity. Again,

there are many paths for a practice to receive a 50 percent score in the quality performance category, so for simplicity we are assuming the score has been calculated. Because the MIPS eligible clinician is non-patient facing, they qualify for special scoring for improvement activities and receive 20 points (out of 40 possible points) for each medium weighted activity. Also, this individual did not submit Promoting Interoperability performance

category measures and qualifies for the automatic redistribution of the Promoting Interoperability performance category weight to the quality performance category. Again, for simplicity, we assume a complex patient bonus of 3 points.

In this example, the final score is 53 and the performance threshold of 30 is exceeded while the additional performance threshold of 80 is not.

TABLE 56—SCORING EXAMPLE 3, NON-PATIENT FACING MIPS ELIGIBLE CLINICIAN

[A] Performance category	[B] Performance score	[C] Category weight	[D] Earned points ([B] * [C] * 100)
Quality	50%	70%	35
Cost	50%	15%	7.5
Improvement Activities	20 out of 40 points for 1 medium weight activity—50%.	15%	7.5
Promoting Interoperability	0%	0% (reweighted to quality)	0
Subtotal (Before Bonus)	50
Complex Patient Bonus	3
Final Score (not to exceed 100).	53

We note that these examples are not intended to be exhaustive of the types of participants nor the opportunities for reaching and exceeding the performance threshold.

k. Third Party Intermediaries

We refer readers to § 414.1400 and the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819) for our previously established policies regarding third party intermediaries.

In this proposed rule, we are proposing to: (1) Define third party intermediary and require third party intermediaries to be based in the U.S.; (2) update certification requirements for data submission; (3) update the definition of Qualified Clinical Data Registry (QCDR); revise the self-nomination period for QCDRs; update of information required for QCDRs at the time of self-nomination; update consideration criteria for approval of QCDR measures; define the topped out timeline for QCDR measures; (4) revise the self-nomination period for qualified registries; (5) define health IT vendor; (6) update the definition, criteria, and requirements for CMS-approved survey vendor; auditing criteria; and (7) revising probation and disqualification criteria. As we continue our efforts to provide flexible and meaningful reporting options for MIPS eligible clinicians and groups, we will expound

on the requirements and functions of a third party intermediary.

(1) Third Party Intermediaries Definition

At § 414.1305, we are proposing a new definition to define a third party intermediary as an entity that has been approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and Promoting Interoperability performance categories. A QCDR, qualified registry, health IT vendor, or CMS-approved survey vendor are considered third party intermediaries. We are also proposing to change the section heading at § 414.1400 from “Third party data submissions” to “Third party intermediaries” to elucidate the definition and function of a third party intermediary.

We have received inquiries from stakeholders regarding the ability of a non-U.S. based third party intermediary to participate in MIPS. CMS IT systems are required to adhere to multiple agency and federal security standards and policy. CMS policy prohibits non-U.S. citizens from accessing CMS IT systems, and also requires all CMS program data to be retained in accordance with U.S. Federal policy, specifically National Institute of Standards and Technology (NIST) Special Publication (SP) 800–63, which

outlines enrollment and identity proofing requirements (levels of assurance) for federal IT system access. Access to the Quality Payment Program would necessitate passing a remote or in-person Federated Identity Proofing process (that is, Equifax or equivalent). A non-U.S. based third party intermediary’s potential lack of a SSN, TIN, U.S. based address, and other elements required for identity proofing and identity verification would impact their ability to pass the necessary background checks. An inability to pass identity proofing may limit or fully deny access to the Quality Payment Program if the intent is to interact with the Quality Payment Program outside of the U.S. for the purposes of reporting and storing data.

We would like to emphasize that these requirements are all tied to existing federal policy which is applicable to all HHS/CMS FISMA systems and assets and are not Quality Payment Program specific. More information on these policies is available here: HHS Information Security and Privacy Policy (IS2P) (<https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/index.html>); CMS Information Systems Security and Privacy Policy (IS2P2) (<https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Info-Security-Library-Items/CMS->

Information-Systems-Security-and-Privacy-Policy-IS2P2.html); OMB Memorandum 04–04, E-Authentication Guidance for Federal Agencies (<https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy04/m04-04.pdf>); and NIST SP 800–63 Digital Identity Guidelines (<https://pages.nist.gov/800-63-3/>). Therefore, we propose to amend previously finalized policies at § 414.1400(a)(4) to indicate that a third party intermediary's principle place of business and retention of associated CMS data must be within the U.S.

We would like to note that third party intermediaries that are authorized by us to submit data on behalf of MIPS eligible clinicians, groups or virtual groups have not otherwise been evaluated for the capabilities, quality, or any other features or its products. The United States Government and CMS do not endorse or recommend any third party intermediary or its products. Prior to selecting or using any third party intermediary or its products, MIPS eligible clinicians, groups or virtual groups should perform their own due diligence on the entity and its products, including contacting the entity directly to learn more about its products.

(2) Certification

We previously finalized in the CY 2018 Quality Payment Program final rule (82 FR 53807) at § 414.1400(a)(5), that all data submitted to us by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary to the best of its knowledge as true, accurate, and complete; and that this certification must occur at the time of the submission and accompany the submission. We have discovered it is not operationally feasible to require certification at the time of submission, or to require that the certification accompany the submission, for submission types by third party intermediaries, including data via direct, login and upload, login and attest, CMS Web Interface or Medicare Part B claims. We refer readers to section III.H.3.h of this proposed rule for our proposed modifications to the previously established data submission terminology. In order to address these various submission types that are currently available, we are proposing to amend § 414.1400(a)(5) to state that all data submitted to CMS by a third party intermediary must be certified as true, accurate, and complete to the best of its knowledge and that such certification must be made in a form and manner and at such time as specified by CMS.

(3) Qualified Clinical Data Registries (QCDRs)

We refer readers to § 414.1400 and the CY 2018 Quality Payment Program final rule (82 FR 53807 through 53815) for our previously finalized policies regarding QCDRs. In this proposed rule, we are proposing to update: The definition of QCDR, the self-nomination period for QCDRs, information required for QCDRs at the time of self-nomination, and consideration of criteria for approval of QCDR measures.

(a) Proposed Update to the Definition of a QCDR

At § 414.1305 and in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364), we finalized the definition of a QCDR to be a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

We want to ensure that QCDRs that participate in MIPS have access to clinical expertise in quality measurement and are able to provide and demonstrate an understanding of the clinical medicine, evidence-based gaps in care, and opportunities for improvement in the quality of care delivered to patients and priorities that are important to MIPS eligible clinicians. From our experiences with QCDRs to date, we have discovered that certain entities that have a predominantly technical background with limited understanding of medical quality metrics or the process for developing quality measures are seeking approval as a QCDR. We recognize the importance of these organizations' expertise within the Quality Payment Program; however, we do not believe that these types of entities, in the absence of clinical expertise in quality measurement, meet the intent of QCDRs. Specifically, we are concerned that the QCDR measures submitted by such entities for approval have not undergone the same consensus development, scientific rigor, and clinical assessment that is needed for developing measures, compared to those QCDR measures that are developed by specialty societies and other entities with clinical expertise.

We refer readers to the CMS Quality Measure Development Plan at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf> for more information regarding

the measure development process. While we have encouraged the participation of entities as QCDRs, during the past two iterations of the self-nomination period, a large number of entities that do not have the necessary clinical expertise to foster quality improvement have self-nominated or indicated their interest in becoming QCDRs. In reviewing previous QCDR measure submissions during the self-nomination and QCDR measure review and approval cycles in MIPS, we have observed that some entities were developing QCDR measures without a complete understanding of measure constructs (such as what is required of a composite measure or what it means to risk-adjust), and in some instances, QCDRs were developing QCDR measures in clinical areas in which they did not have expertise. We believe that with the increasing interest in QCDR development, it is important to ensure that QCDRs that participate in MIPS are first and foremost in business to improve the quality of care clinicians provide to their patients through quality measurement and/or disease tracking. An added benefit for QCDR participants is providing reliable quality reporting options for quality reporting programs for clinicians and specialists. Therefore, beginning with the 2022 MIPS payment year, we propose to amend § 414.1305 to modify the definition of a QCDR to state that the approved entity must have clinical expertise in medicine and quality measure development. As a part of the self-nomination process, we would look for entities that have quality improvement expertise and a clinical background. We would also follow up with the entity via, for example, email or teleconference, should we question whether or not our standards are met. Specifically, a QCDR would be defined as an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. In addition, under § 414.1400(b)(2)(ii), an entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR as long as the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR. Thus, we expect entities without clinical expertise in medicine and

quality measure development that want to become QCDRs would collaborate or align with entities with such expertise in accordance with § 414.1400(b)(2)(ii). However, such entities may seek to qualify as another type of third party intermediary, such as a qualified registry. Becoming a registry does not require the level of measure development expertise that is needed to be a QCDR that develops measures.

(b) Establishment of an Entity Seeking To Qualify as a QCDR

In the CY 2017 Quality Payment Program final rule (81 FR 77364), we require at § 414.1400 (c)(2) that the QCDR must have at least 25 participants by January 1 of the performance period. These participants do not need to use the QCDR to report MIPS data to us; rather, they need to submit data to the QCDR for quality improvement. We realize that a QCDR's lack of preparedness to accept data from MIPS eligible clinicians and groups beginning on January 1 of the performance period may negatively impact a clinician's ability to use a QCDR to report, monitor the quality of care they provide to their patients (and act on these results) and may inadvertently increase clinician burden. For these reasons, we are proposing to redesignate § 414.1400 (c)(2) as § 414.1400(b)(2)(i) to state that beginning with the 2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the performance period. These participants do not need to use the QCDR to report MIPS data to us; rather, they need to submit data to the QCDR for quality improvement.

(c) Self-Nomination Process

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53808 through 53813) for our previously established policies regarding the simplified self-nomination process for existing QCDRs in MIPS that are in good standing and web-based submission of self-nomination forms. We are not proposing any changes to those policies in this proposed rule; however, we are proposing to update: (1) The self-nomination period; and (2) information required at the time of self-nomination.

(i) Self-Nomination Period

Under § 414.1400(b), QCDRs must self-nominate from September 1 of the year prior to the applicable performance period until November 1 of the same year and must, among other things, provide all information requested by us at the time of self-nomination. As indicated in the CY 2017 Quality

Payment Program final rule (81 FR 77366), our goal has been to publish the list of approved QCDRs along with their approved QCDR measures prior to the beginning of the applicable performance period.

We have received feedback from entities that have self-nominated to be a QCDR about the need for additional time to respond to requests for information during the review process, particularly with respect to QCDR measures that the entity intends to submit to us for the applicable performance period. In addition, based on our observations of the previous two self-nomination cycles, we anticipate an increase in the number of QCDR measure submissions for our review and consideration. For the transition year of MIPS, we received over 1,000 QCDR measure submissions for review, and for the CY 2018 performance period, we received over 1,400 QCDR measure submissions. In order for us to process, review, and approve the QCDR measure submissions and provide QCDRs with sufficient time to respond to requests for information during the review process, while still meeting our goal to publish the list of approved QCDRs along with their approved QCDR measures prior to the start of the applicable performance period, we believe that an earlier self-nomination period is needed.

Therefore, we are proposing to update the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1. Therefore, we are also proposing to amend § 414.1400(b)(1) to provide that, beginning with the 2022 MIPS payment year, entities seeking to qualify as QCDRs must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process. For example, for the 2022 MIPS payment year, the applicable performance period would be CY 2020, as discussed in section III.H.3.g. of this proposed rule. Therefore for the CY 2020 performance period, the self-nomination period would begin on July 1st, 2019 and end on September 1st, 2019, and we will make QCDRs aware of this through our normal communication channels. We believe that updating the self-nomination period would allow for additional

review time and measure discussions with QCDRs.

(ii) Information Required at the Time of Self-Nomination

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53814), where we finalized that as a part of the self-nomination review and approval process for the CY 2018 performance period and future years, we will assign QCDR measure IDs to approved QCDR measures, and the same measure ID must be used by any other QCDRs that have received permission to also report the measure. We have received some questions from stakeholders as to whether the QCDR measure ID must be utilized or whether it is optional. As stated in the CY 2018 Quality Payment Program final rule, QCDRs, including any other QCDRs that have received permission to also report the measure, must use the CMS-assigned QCDR measure ID. It is important that the CMS-assigned QCDR measure ID is posted and used accordingly, because without this ID we are not able to accurately identify and calculate the QCDR measures according to their specifications. Therefore, we propose to update § 414.1400(b)(3)(iii) to state that QCDRs must include their CMS-assigned QCDR measure ID number when posting their approved QCDR measure specifications, and also when submitting data on the QCDR measures to us.

(d) QCDR Measure Requirements

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375) for where we previously finalized standards and criteria used for selecting and approving QCDR measures. We finalized that QCDR measures must: Provide specifications for each measure, activity, or objective the QCDR intends to submit to CMS; and provide CMS descriptions and narrative specifications for each measure, activity, or objective no later than November 1 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (improvement activities and Promoting Interoperability) data starting with the 2018 performance period and in future program years. We are proposing to consolidate our previously finalized standards and criteria used for selecting and approving QCDR measures at § 414.1400(e) and (f) at § 414.1400(b)(3). In this proposed rule, we are proposing to apply certain criteria used under the Call for Quality Measures Process when considering QCDR measures for possible

inclusion in MIPS beginning with the MIPS 2021 payment year.

In the CY 2018 Quality Payment Program final rule (82 FR 53814), we noted our interest in elevating the standards for which QCDR measures are selected and approved for use and sought comment on whether the standards and criteria used for selecting and approving QCDR measures should be more closely aligned with those used for the Call for Quality Measures process described in the CY 2017 Quality Payment Program final rule (81 FR 77151). Some commenters expressed concern with this alignment, stating that the Call for Measures process is cumbersome, and would increase burden. Other commenters expressed the belief that the Call for Measures process does not recognize the uniqueness of QCDRs, and is not agile. We would like to clarify that our intention with any future alignment is to work towards consistent standards and evaluation criteria that would be applicable to all MIPS quality measures, including QCDR measures. We understand that some of the criteria under the Call for Measures process may be difficult for QCDRs to meet prior to submitting a particular measure for approval; however, we believe that the criteria under the Call for Measures process helps ensure that any new measures are reliable and valid for use in the program. Having a greater alignment in measure standards helps ensure that MIPS eligible clinicians and groups are able to select from an array of measures that are considered to be higher quality and provide meaningful measurement. As such, we believe that as we gain additional experience with QCDRs in MIPS, it would be appropriate to further align these criteria for QCDR measures with those of MIPS quality measures in future program years.

Therefore, in addition to the QCDR measure criteria previously finalized at § 414.1400(f), we are proposing to apply select criteria used under the Call for Measures Process, as described in the CY 2018 Quality Payment Program final rule (82 FR 53636). Specifically, in addition to the QCDR measure criteria at proposed § 414.1400(b)(3), we propose to apply the following criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.

- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost and resource use.
- Measures that address significant variation in performance.

We believe that as we gain additional experience with QCDRs in MIPS, it would be appropriate to further align these criteria for QCDR measures with those of MIPS quality measures in future program years.

(e) QCDRs Seeking Permission From Another QCDR To Use an Existing, Approved QCDR Measure

In the CY 2018 Quality Payment Program final rule (82 FR 53813), we finalized that beginning with the 2018 performance period and for future program years, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. We intended for this policy to help reduce the number of QCDR measures that are similar in concept or clinical topic, or duplicative of other QCDR measures that are being approved. Furthermore, having multiple QCDRs report on the same QCDR measure allows for a larger cohort of clinicians to report on the measure, which helps establish more reliable benchmarks and may give some eligible clinicians or group a better chance of obtaining a higher score on a particular measure. However, we have experienced that this policy has created unintended financial burden for QCDRs requesting permission from other QCDRs who own QCDR measures, as some QCDRs charge a fee for the use of their QCDR measures. MIPS quality measures, while stewarded by specific specialty societies or organizations, are generally available for third party intermediaries, MIPS eligible clinicians, and groups to report on for purposes of MIPS without a fee for use. Similarly, we believe, that once a QCDR measure is approved for reporting in MIPS, it should be generally available for other QCDRs to report on for purposes of MIPS without a fee for use. We propose at § 414.1400 (b)(3)(ii)(C) that beginning with the 2021 MIPS payment year, as a condition of a QCDR measure's approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year. We also propose at

§ 414.1400(b)(3)(iii) that other QCDRs would be required to use the same CMS-assigned QCDR measure ID. If a QCDR refuses to enter into such a license agreement, the QCDR measure would be rejected and another QCDR measure of similar clinical concept or topic may be approved in its place.

(4) Qualified Registries

We refer readers to § 414.1400 and the CY 2018 Quality Payment Program final rule (82 FR 53815 through 53818) for our previously finalized policies regarding qualified registries. In this rule, we are proposing to update: Information required for qualified registries at the time of self-nomination and the self-nomination period for qualified registries. This is discussed in more detail below.

(a) Establishment of an Entity Seeking To Qualify as a Qualified Registry

In the CY 2017 Quality Payment Program final rule (81 FR 77383), we state at § 414.1400(h)(2) that the qualified registry must have at least 25 participants by January 1 of the performance period. These participants do not need to use the qualified registry to report MIPS data to us; rather, they need to submit data to the qualified registry for quality improvement. We realize that a qualified registry's lack of preparedness to accept data from MIPS eligible clinicians and groups beginning on January 1 of the performance period may negatively impact a clinician's ability to use a Qualified Registry to report, monitor the quality of care they provide to their patients (and act on these results) and may inadvertently increase clinician burden. For these reasons, we are proposing to redesignate § 414.1400(h)(2) as § 414.1400(c)(2) to state that beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period. These participants do not need to use the qualified registry to report MIPS data to us; rather, they need to submit data to the qualified registry for quality improvement.

(b) Self-Nomination Process

We refer readers to § 414.1400(g), the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77383 and 82 FR 53815, respectively) for our previously established policies regarding the self-nomination process for qualified registries. We are not proposing any changes to this policy.

(c) Self-Nomination Period

Under the previously finalized policy at § 414.1400(g), qualified registries must self-nominate from September 1 of the year prior to the applicable performance period until November 1 of the same year and must, among other things, provide all information requested by us at the time of self-nomination. To maintain alignment with the timelines proposed for QCDR self-nomination, as discussed in section III.H.3.k.(3)(c) above, we are also proposing to update the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1. Specifically, we are proposing at § 414.1400(c)(1) that, beginning with the 2022 MIPS payment year, entities seeking to qualify as qualified registries must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process. For example, for the 2022 MIPS payment year, the applicable performance period would be CY 2020, as discussed in section III.H.3.g. of this proposed rule. Therefore, the self-nomination period for qualified registries would begin on July 1, 2019 and end on September 1, 2019.

(5) Health IT Vendors or Other Authorized Third Parties That Obtain Data From MIPS Eligible Clinicians' Certified EHR Technology (CEHRT)

We refer readers to § 414.1400 and the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382) for our previously finalized policies regarding health IT vendors or other authorized third parties that obtain data from MIPS eligible clinicians. We finalized that health IT vendors that obtain data from a MIPS eligible clinician, like other third party intermediaries, would have to meet all criteria designated by us as a condition of their qualification or approval to participate in MIPS as a third party intermediary. This includes submitting data in the form and manner specified by us. We propose to codify these policies at § 414.1400(d). Although we specified criteria for a health IT vendor in the CY 2017 Quality Payment Program final rule, we failed to codify the definition of a health IT vendor. Therefore, in this proposed rule, we are

proposing to define at § 414.1305, that health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT).

As indicated in footnote 1 of the CY 2017 Quality Payment Program final rule (81 FR 77014 through 77015), the term "health IT vendor" encompasses many types of entities that support the health IT requirements on behalf of a MIPS eligible clinician. A "health IT vendor" may or may not also be a "health IT developer" for the purposes of the ONC Health IT Certification Program (Program), and, in some cases, the developer and the vendor of a single product may be different entities. Under the Program, a health IT developer constitutes a vendor, self-developer, or other entity that presents health IT for certification or has health IT certified under the Program. Other health IT vendors may maintain a range of data transmission, aggregation, and calculation services or functions, such as organizations which facilitate health information exchange.

(6) CMS-Approved Survey Vendors

In the CY 2017 Quality Payment Program final rule (81 FR 77386), we finalized the criteria, required forms, and vendor business requirements needed to participate in MIPS as a CMS-approved survey vendor. In this proposed rule, we are proposing at § 414.1400(e) to codify these previously finalized criteria and requirements. Accordingly, we propose that § 414.1400(e) would state that entities seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. The application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. We propose that a CMS-approved survey vendor must meet several criteria. First, an entity must have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

- At least 3 years of experience administering mixed-mode surveys (surveys that employ multiple modes to collect data) that include mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);
- At least 3 years of experience administering surveys to a Medicare population;

- At least 3 years of experience administering CAHPS surveys within the past 5 years;

- Experience administering surveys in English and one of the following languages: Cantonese, Korean, Mandarin, Russian, or Vietnamese;

- Use of equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule callbacks to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and

- Employ a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

Furthermore, we propose that to be a CMS-approved survey vendor, the entity must also meet the following criteria: It must have certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data; the entity must have successfully completed, and required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors; the entity must have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts; the entity must have agreed to participate and cooperate, and have required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors; and the entity must have sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

We also refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53818 through 53819) for our previously established policies regarding the updated survey vendor application deadline.

(7) Auditing of Third Party Intermediaries Submitting MIPS Data

In the CY 2018 Quality Payment Program final rule (82 FR 53819), we established policies regarding auditing of third party intermediaries submitting MIPS data. In this proposed rule, we are not proposing any changes to these policies.

(8) Remedial Action and Termination of Third Party Intermediaries

In the CY 2017 Quality Payment Program final rule (81 FR 77548), we finalized the criteria for probation and disqualification for third party intermediaries at § 414.1400(k). In this proposed rule, we are proposing to revise the numbering of this section and the title to more accurately describe the policies in this section. Thus, we propose to renumber this section as § 414.1400(f) and to rename it as “remedial action and termination of third party intermediaries.”

Additionally, we are proposing changes to § 414.1400(f) to amend, clarify, and streamline our policies related to remedial action and termination.

Our intent with these policies is to identify noncompliance with the applicable third party intermediary criteria, as well as identify issues that may impact the accuracy of our ability to use the data submitted by third party intermediaries. Accordingly, we propose to amend § 414.1400(f)(1) to state that we may take remedial action for noncompliance with applicable third party intermediary criteria for approval (a deficiency) or for the submission of inaccurate, unusable, or otherwise compromised data. In the CY 2017 Quality Payment Program final rule, we finalized our policy regarding data inaccuracies at § 414.1400(k)(4). We are proposing at § 414.1400(f)(3) to expand data inaccuracies to include a determination by us that data is inaccurate, unusable, or otherwise compromised. However, we are not proposing to change the factors we may consider to make such a determination. We also propose to move the notification requirement at § 414.1400(k)(6) to § 414.1400(f)(1) and to apply the requirement to all deficiencies and data errors.

Based on our early experience with third party intermediaries under MIPS and the challenges for both third party intermediaries and us in regards to timing and trying to resolve deficiencies and data errors within the various reporting and performance periods, we propose to amend the timeframes by which a third party intermediary must submit a Corrective Action Plan (CAP) to us or come into compliance. Specifically, we propose § 414.1400(f)(2), which requires third party intermediaries to submit a CAP or correct the deficiencies or data errors by the date specified by us.

Additionally, we propose to consolidate the grounds by which we can take remedial action against a third party intermediary found at

§ 414.1400(k)(1) and (4) into § 414.1400(f)(1), as well as the grounds by which we can terminate a third party intermediary found at § 414.1400(k)(3), (5) and (7) into § 414.1400(f)(2).

Therefore, we propose at § 414.1400(f)(1) that if at any time we determine that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, or has submitted data that is inaccurate, unusable, or otherwise compromised, we may take certain remedial actions (for example, request a Corrective Action Plan (CAP)). In addition, we propose at § 414.1400(f)(2) that we may terminate, immediately or with advance notice, the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the following reasons: We have grounds to impose remedial action, we have not received a CAP within the specified time period or the CAP is not accepted by us, or the third party intermediary fails to correct the deficiencies or data errors by the date specified by us.

Finally, we propose to consolidate the actions we may take if we identify a deficiency or data error that are set forth at § 414.1400(k)(3) and (7) into § 414.1400(f)(1). Thus, we propose at § 414.1400(f)(1) that if we determine a third party intermediary has ceased to meet one or more of the applicable criteria for approval, or has submitted data that is inaccurate, unusable, or otherwise compromised, we may require the third party intermediary to submit a CAP to us to address the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring. The CAP must be submitted to CMS by a date specified by CMS. We propose that CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if the submitted data: (1) Includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and (2) affects more than three percent (but less than 5 percent) of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary. In addition, we propose that if the third party intermediary has a data error rate of 3 percent or more, we will publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

We also propose to amend § 414.1400(k) by removing our probation policy. Therefore, we propose to remove the definition of probation at

§ 414.1400(k)(2) and references to probation in § 414.1400(k)(1), (3) and (5).

1. Public Reporting on Physician Compare

This section contains our proposed policies for public reporting on Physician Compare for year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) and future years, including MIPS, APMs, and other information as required by the MACRA and building on our previously finalized public reporting policies (see 82 FR 53819 through 53832).

Physician Compare (<http://www.medicare.gov/physiciancompare>) draws its operating authority from section 10331(a)(1) of the Affordable Care Act. Consistent with section 10331(a)(2) of the Affordable Care Act, Physician Compare initiated a phased approach to publicly reporting performance scores that provide comparable information on quality and patient experience measures. A complete history of public reporting on Physician Compare is detailed in the CY 2016 PFS final rule (80 FR 71117 through 71122). More information about Physician Compare, including the history of public reporting and regular updates about what information is currently available, can also be accessed on the Physician Compare Initiative website at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/>.

As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53820), Physician Compare has continued to pursue a phased approach to public reporting under the MACRA in accordance with section 1848(q)(9) of the Act. Generally, all data available for public reporting on Physician Compare must meet our established public reporting standards under § 414.1395(b). In addition, for each program year, CMS provides a 30-day preview period for any clinician or group with Quality Payment Program data before the data are publicly reported on Physician Compare under § 414.1395(d). All data available for public reporting—measure rates, scores, and attestations, objectives, etc.—are available for review and correction during the targeted review process. See the CY 2018 Quality Payment Program final rule for details on this process (82 FR 53820).

Lastly, section 104(e) of the MACRA requires the Secretary to make publicly available, on an annual basis, in an easily understandable format, information for physicians and, as

appropriate, other eligible clinicians related to items and services furnished to Medicare beneficiaries under Title XVIII of the Act. In accordance with section 104(e) of the MACRA, we finalized a policy in the CY 2016 PFS final rule (80 FR 71131) to add utilization data to the Physician Compare downloadable database.

We believe section 10331 of the Affordable Care Act supports the overarching goals of the MACRA by providing the public with performance information that will help them make informed decisions about their health care, while encouraging clinicians to improve the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, section 1848(q)(9) of the Act, and section 104(e) of the MACRA, we plan to continue to publicly report performance information on Physician Compare. As such, the following sections discuss the information previously finalized for inclusion on Physician Compare for all program years, as well as our proposed policies for public reporting on Physician Compare for year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) and future years.

(1) Final Score, Performance Categories, and Aggregate Information

In the CY 2018 Quality Payment Program final rule (82 FR 53823), we finalized a policy to publicly report on Physician Compare, either on profile pages or in the downloadable database, the final score for each MIPS eligible clinician and the performance of each MIPS eligible clinician for each performance category, and to periodically post aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category, as technically feasible, for all future years. We will use statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel convened by our contractor, to determine how and where these data are best reported on Physician Compare.

A summary of the previously finalized policies related to each performance category of MIPS data, as well as proposed policies for year 3 and future years, follows. It is important to note just because performance information is available for public reporting, it does not mean all data under all performance categories will be included on either public-facing profile pages or the downloadable database.

These data must meet the public reporting standards, first. And, second, we are careful to ensure that we do not include too much information on public-facing profile pages in an effort not to overwhelm website users. Although all information submitted under MIPS is technically available for public reporting, we will continue our phased approach to making this information public.

(2) Quality

In the CY 2018 Quality Payment Program final rule (82 FR 53824), we finalized a policy to make all measures under the MIPS quality performance category available for public reporting on Physician Compare, either on profile pages or in the downloadable database, as technically feasible. This includes all available measures across all collection types for both MIPS eligible clinicians and groups, for all future years. We will use statistical testing and website user testing to determine how and where measures are reported on Physician Compare. We will not publicly report first year quality measures, meaning any measure in its first year of use in the quality performance category, under § 414.1395(c). We will also include the total number of patients reported on for each measure included in the downloadable database (82 FR 53824).

We propose to modify § 414.1395(b) to reference “collection types” instead of “submission mechanisms” to accurately update the terminology. We also propose to revise § 414.1395(c) to indicate that we will not publicly report first year quality measures for the first 2 years a measure is in use in the quality performance category. We propose this change to encourage clinicians and groups to report new measures, get feedback on those measures, and learn from the early years of reporting measures before measure are made public. We request comment on these proposals.

(3) Cost

In the CY 2018 Quality Payment Program final rule (82 FR 53825), we finalized a policy to include on Physician Compare a subset of cost measures that meet the public reporting standards at § 414.1395(b), either on profile pages or in the downloadable database, if technically feasible, for all future years. This includes all available cost measures, and applies to both MIPS eligible clinicians and groups. We will use statistical testing and website user testing to determine how and where measures are reported on Physician Compare. We previously finalized that we will not publicly report first year

cost measures, meaning any measure in its first year of use in the cost performance category, under § 414.1395(c). Consistent with our proposal for first year quality measures, we propose to revise § 414.1395(c) to indicate that we will not publicly report first year cost measures for the first 2 years a measure is in use in the cost performance category. We propose this change to help clinicians and groups get feedback on these measures and learn from the early years of these new measures being calculated before measure are made public. We request comment on this proposal.

(4) Improvement Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53826), we finalized a policy to include a subset of improvement activities information on Physician Compare, either on the profile pages or in the downloadable database, if technically feasible, for all future years. This includes all available activities reported via all available collection types, and applies to both MIPS eligible clinicians and groups. For those eligible clinicians and groups that successfully meet the improvement activities performance category requirements, this information will be posted on Physician Compare as an indicator. We also finalized for all future years to publicly report first year activities if all other public reporting criteria are satisfied.

(5) Promoting Interoperability (PI)

In the CY 2018 Quality Payment Program final rule (82 FR 53827), we finalized a policy to include an indicator on Physician Compare for any eligible clinician or group who successfully meets the Promoting Interoperability performance category, as technically feasible, for all future years. “Successful” performance is defined as obtaining the base score of 50 percent (82 FR 53826). We also finalized a policy to include on Physician Compare, either on the profile pages or in the downloadable database, as technically feasible, additional information, including, but not limited to, objectives, activities, or measures specified in the CY 2018 Quality Payment Program final rule (82 FR 53827; see 82 FR 53663 through 53688). This includes all available objectives, activities, or measures reported via all available collection types, and applies to both MIPS eligible clinicians and groups (82 FR 53827). We will use statistical testing and website user testing to determine how and where objectives, activities, and measures are reported on Physician Compare. We also

finalized for all future years to publicly report first year Promoting Interoperability objectives, activities, and measures if all other public reporting criteria are satisfied.

In addition, we finalized that we will indicate “high” performance, as technically feasible and appropriate, in year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019). “High” performance is defined as obtaining a score of 100 percent (82 FR 53826 through 53827).

As the Quality Payment Program progresses into year 3, and consistent with our work to simplify the requirements under the Promoting Interoperability performance category of MIPS, we are proposing not to include the indicator of “high” performance and to maintain only an indicator for “successful” performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019). Not including the “high” performance indicator while maintaining the “successful” performance indicator continues to provide useful information to patients and caregivers without burdening website users with the additional complexity of accurately differentiating between “successful” and “high” performance, as this proved difficult for users in testing. User testing to date shows that website users value this information overall, however, as they appreciate knowing clinicians and groups are effectively using EHR technology to improve care quality.

We request comment on our proposal not to include the indicator for “high” performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019).

We are also seeking comment only on the type of EHR utilization performance information stakeholders would like CMS to consider adding to Physician Compare. This information would be considered for possible future inclusion on the website.

(6) Achievable Benchmark of Care (ABC™)

Benchmarks are important to ensuring that the quality data published on Physician Compare are accurately understood. A benchmark allows website users to more easily evaluate the information published by providing a point of comparison between groups and between clinicians. In the CY 2018 Quality Payment Program final rule (82 FR 53829), we finalized a policy to use

the Achievable Benchmark of Care (ABC™) methodology to determine a benchmark for the quality, cost, improvement activities, and Promoting Interoperability data, as feasible and appropriate, by measure and collection type for each year of the Quality Payment Program based on the most recently available data each year. We also finalized a policy to use this benchmark as the basis of a 5-star rating for each available measure, as feasible and appropriate. For a detailed discussion of the ABC™ methodology, and more information about how this benchmark together with the equal ranges method is currently used to determine the 5-star rating system for Physician Compare, see the CY 2018 Quality Payment Program final rule (82 FR 53827 through 53829). Additional information, including the Benchmark and Star Rating Fact Sheet, can be found on the Physician Compare Initiative website (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/index.html>).

(a) Historical Data-Based Benchmarks

Benchmarks, and the resulting star rating, are valuable tools for patients and caregivers to use to best understand the performance information included on Physician Compare. Benchmarks can also help the clinicians and groups reporting performance information understand their performance relative to their peers, and therefore, help foster continuous quality improvement. In the initial years of the Quality Payment Program, we anticipated year-to-year changes in the measures available. As noted, we previously finalized a policy to determine the benchmark using the most recently available data (82 FR 53829). This ensured that a benchmark could be calculated despite potential year-to-year measure changes, but it also meant that the benchmark was not known to clinicians and groups prior to the performance period.

By year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020), we expect enough year-to-year stability in the measures available for reporting across all MIPS performance categories to use historical data to produce a reliable and statistically sound benchmark for most measures, by measure and collection type. Therefore, we are proposing to modify our existing policy to use the ABC™ methodology to determine benchmarks for the quality, cost, improvement activities, and Promoting Interoperability performance categories based on historical data, as feasible and appropriate, by measure and collection

type beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020). Specifically, benchmarks would be based on performance data from a baseline period or, if such data is not available, performance data from the performance period. The baseline period would be the 12-month calendar year that is 2 years prior to the applicable performance period. The benchmarks would be published prior to the start of the performance period, as technically feasible. For example, for the CY 2019 performance period, the benchmark developed using the ABC™ methodology would be calculated using CY 2017 performance period data and would be published by the start of CY 2019, as feasible and appropriate. If historical data is not available for a particular measure, we would indicate that and calculate the benchmark using performance data from the performance period. In this example, we would use CY 2019 performance period data to calculate the benchmark for CY 2019 performance period measures, as needed. This approach of utilizing historical data would be consistent with how the MIPS benchmarks are calculated for purposes of scoring the quality performance category. But, most importantly, this approach would provide eligible clinicians and groups with valuable information about the benchmark to meet to receive a 5-star rating on Physician Compare before data collection starts for the performance period. We request comment on this proposal.

(b) QCDR Measure Benchmarks

Currently, only MIPS measures are star rated on Physician Compare. QCDR measures, as that term is used in § 414.1400(e), are publicly reported as percent performance rates. As more QCDR measure data is available for public reporting, and appreciating the value of star rating the measures presented to website users, we believe star rating the QCDR measures will greatly benefit patients and caregivers as they work to make informed health care decisions. Particularly in the quality performance category, we believe that reporting all measure data in the same way will ease the burden of interpretation placed on site users and make the data more useful to them. Therefore, we are proposing to further modify our existing policy to extend the use of the ABC™ methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures, as that term is used in proposed § 414.1400(b)(3), as feasible

and appropriate, using current performance period data in year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019), and using historical benchmark data when possible as proposed above, beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020). We request comment on this proposal.

(7) Voluntary Reporting

In the CY 2018 Quality Payment Program final rule (82 FR 53830), we finalized a policy to make available for public reporting all data submitted voluntarily across all MIPS performance categories, regardless of collection type, by eligible clinicians and groups that are not subject to the MIPS payment adjustments, as technically feasible, for all future years. If an eligible clinician or group that is not subject to the MIPS payment adjustment chooses to submit data on quality, cost (if applicable), improvement activities, or Promoting Interoperability, these data are available for public reporting. We also finalized that during the 30-day preview period, these eligible clinicians and groups may opt out of having their data publicly reported on Physician Compare (82 FR 53830). If these eligible clinicians and groups do not opt out during the 30-day preview period, their data will be available for inclusion on Physician Compare if the data meet all public reporting standards at § 414.1395(b).

(8) APM Data

In the CY 2018 Quality Payment Program final rule (82 FR 53830), we finalized a policy to publicly report the names of eligible clinicians in Advanced APMs and the names and performance of Advanced APMs and APMs that are not considered Advanced APMs related to the Quality Payment Program, such as Track 1 Shared Savings Program Accountable Care Organizations (ACOs), as technically feasible, for all future years. We also finalized a policy to link clinicians and groups and the APMs they participate in on Physician Compare, as technically feasible.

4. Overview of the APM Incentive

a. Overview

Section 1833(z) of the Act requires that an incentive payment be made to QPs for achieving threshold levels of participation in Advanced APMs. In the CY 2017 Quality Payment Program final rule (81 FR 77399 through 77491), we finalized the following policies:

- Beginning in 2019, if an eligible clinician participated sufficiently in an Advanced APM during the QP

Performance Period, that eligible clinician may become a QP for the year. Eligible clinicians who are QPs are excluded from the MIPS reporting requirements for the performance year and payment adjustment for the payment year.

- For years from 2019 through 2024, QPs receive a lump sum incentive payment equal to 5 percent of their prior year's estimated aggregate payments for Part B covered professional services. Beginning in 2026, QPs receive a higher update under the PFS for the year than non-QPs.

- For payment years 2019 and 2020, eligible clinicians may become QPs only through participation in Advanced APMs.

- For payment years 2021 and later, eligible clinicians may become QPs through a combination of participation in Advanced APMs and Other Payer Advanced APMs (which we refer to as the All-Payer Combination Option).

In this proposed rule, we discuss proposals for clarifications and modifications to some of the policies that we previously finalized pertaining to Advanced APMs and the All-Payer Combination Option.

b. Terms and Definitions

As we continue to develop the Quality Payment Program, we have identified the need to propose changes to some of the previously finalized definitions. A complete list of the original definitions is available in the CY 2017 Quality Payment Program final rule (81 FR 77537 through 77540).

In the CY 2018 Quality Payment Program final rule, in order to consolidate our regulations and avoid unnecessarily defining a term, we finalized removal of the defined term for “Advanced APM Entity” in § 414.1305 and replaced instances of that term throughout the regulation with “APM Entity.” Similarly, we finalized replacing “Advanced APM Entity group” with “APM Entity group” where it appears throughout our regulations (82 FR 53833). We noted that these changes were technical and had no substantive effect on our policies.

To further consolidate our regulations and to clarify any potential ambiguity, we propose to modify the definition of Qualifying APM Participant (QP) at § 414.1305 to provide that a QP is an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold for the year based on participation in or with an APM Entity that is participating in an Advanced APM. The current definition of QP is based on an eligible clinician's

participation in an Advanced APM Entity, which no longer is a defined term. Simply replacing the term “Advanced APM Entity” with the term “APM Entity” as finalized in the CY 2018 Quality Payment Program final rule does not fully convey the definition of QP because, as previously noted at 82 FR 53833, an APM Entity can participate in an APM that is, or is not, an Advanced APM; and QP status is attainable only through participation in an Advanced APM. Again we note that this proposed change is technical and would not have a substantive effect on our policies.

d. Advanced APMs

(1) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that:

- Requires its participants to use certified EHR technology (CEHRT) (81 FR 77409 through 77414);
- Provides for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS (81 FR 77414 through 77418); and
- Either requires its participating APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount, or is a Medical Home Model expanded under section 1115A(c) of the Act (81 FR 77418 through 77431). We refer to this criterion as the financial risk criterion.

(2) Use of CEHRT

(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized that an Advanced APM must require at least 50 percent of eligible clinicians in each APM Entity to use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals. Further, we proposed but did not finalize an increase to the requirement wherein Advanced APMs must require 75 percent CEHRT use in the subsequent year. Instead we maintained the 50 percent CEHRT use requirement for the second performance year and beyond and indicated that we would consider making any potential changes through future rulemaking (81 FR 77412).

As we move into the third year of the Quality Payment Program, we have prioritized interoperability which we consider to be health information

technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable law; and does not constitute information blocking as also defined by the 21st Century Cures Act. As such, we are committed to working with the ONC on implementation of the interoperability provisions of the 21st Century Cures Act. We also are exploring opportunities to incorporate these goals into the design of alternative payment models, wherever feasible and appropriate, to further promote the seamless and secure exchange of health information for clinicians and patients.

(b) Increasing the CEHRT Use Criterion for Advanced APMs

We are now proposing that, beginning for CY 2019, in order to be an Advanced APM, the APM must require at least 75 percent of eligible clinicians in each APM Entity use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals.

According to data collected by ONC, since the CY 2017 Quality Payment Program final rule was published, EHR adoption has been widespread and we want to encourage continued adoption. Additionally, in response to the CY 2017 Quality Payment Program proposed rule stakeholders encouraged us to raise the CEHRT use criterion to 75 percent (see 81 FR 77411). We believe that this proposed change aligns with the increased adoption of CEHRT among providers and suppliers that is already happening, and will encourage further CEHRT adoption. We further believe that most existing Advanced APMs already include provisions that would require participants to adhere to the level of CEHRT use specified in our regulations, and therefore this increase will not negatively impact the Advanced APM status of those APMs.

We seek comment on this proposal.

(3) MIPS Comparable Quality Measures

(a) Overview

In the CY 2017 Quality Payment Program final rule, we explained that one of the criteria for an APM to be an Advanced APM is that it must provide for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(A) of the Act, which

is the MIPS quality performance category. We generally refer to these measures in the remainder of this discussion as “MIPS-comparable quality measures.” We also explained that we interpret this criterion to require the APM to incorporate quality measure results as a factor when determining payment to participants under the terms of the APM (81 FR 77414).

In the CY 2017 Quality Payment Program proposed rule, we proposed that to be an Advanced APM, an APM must base payment on quality measures that are evidence-based, reliable, and valid; and that at least one measure must be an outcome measure unless there is not an applicable outcome measure on the MIPS quality list at the time the APM is developed. The required outcome measure does not have to be one of those on the MIPS quality measure list. We did not specify that the outcome measure is required to be evidence-based, reliable, and valid. (81 FR 28302). We finalized these policies in the CY 2017 Quality Payment Program final rule and codified at § 414.1415(b).

(b) General Quality Measures: Evidence-Based, Reliable, and Valid

We considered a number of ways to implement the Advanced APM criterion that payment must be based on MIPS-comparable quality measures, as well as how to define which measures would reflect the statutory requirements to be “comparable” to MIPS quality measures. We explored options for defining MIPS-comparable quality measures, including: (1) Limiting comparable measures to those from the annual MIPS list of measures; and (2) including measures that have an evidence-based focus and are found to be reliable and valid through measure testing. We concluded that while these potential approaches have merit, they may be overly restrictive for the variety of APMs, which are intended to have the flexibility to test new ways of paying for and delivering care (81 FR 28301 through 28302).

In light of this, we finalized a framework for identifying MIPS-comparable quality measures that was intended to reflect a few key principles: Specifically, that the measure framework would require measures with an evidence-based focus that are reliable and valid, while not being so restrictive as to limit the APMs from using new or innovative measures (81 FR 28302).

Specifically, in the CY 2017 Quality Payment Program final rule, we codified at § 414.1415(b)(2) that at least one of the quality measures upon which an Advanced APM bases the payment must

have an evidence-based focus, be reliable, and valid, and meet at least one of the following criteria: Used in the MIPS quality performance category as described in § 414.1330; endorsed by a consensus-based entity; developed under section 1848(s) of the Act; Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid.

It has come to our attention that some have interpreted § 414.1415(b)(2) to mean that measures on the MIPS final list or submitted in response to the MIPS Call for Quality Measures necessarily are MIPS-comparable quality measures, even if they are not evidence-based, reliable, and valid. We did not intend to imply that any measure that was merely submitted in response to the annual call for quality measures or developed using Quality Payment Program funding would automatically qualify as MIPS-comparable even if the measure was never endorsed by a consensus-based entity, adopted under MIPS, or otherwise determined to be evidence-based, reliable, and valid. While we believe such measures may be evidence-based, reliable, and valid, we did not intend to consider them so for purposes of § 414.1415(b)(2) without independent verification by a consensus-based entity, or based on our own assessment and determination, that they are evidence-based, reliable, and valid. We further believe the same principle applies to Qualified Clinical Data Registry (QCDR) measures. If QCDR measures are endorsed by a consensus-based entity they are presumptively considered MIPS-comparable quality measures for purposes of § 414.1415(b)(2); otherwise we would have needed independent verification, or to make our own assessment and determination, that the measures are evidence-based, reliable, and valid before considering them to be MIPS-comparable quality measures (see 81 FR 77415 through 77417).

Because of the potential ambiguity in the existing definition and out of an abundance of caution in order to avoid any adverse impact on APM entities, eligible clinicians, or other stakeholders, we have used the more permissive interpretation of the regulation text, wherein measures developed under section 1848(s) of the Act and submitted in response to the MIPS Call for Quality Measures will meet the quality criterion in implementing the program thus far, and intend to use this interpretation for the 2019 QP Performance Period until our new proposal described below is

effective on January 1, 2020.

Recognizing that APMs and other payer payment arrangements that we might consider for Advanced APM and Other Payer Advanced APM determinations are well into development for 2019, we are proposing to amend our regulation at § 414.1415(b)(2) to be effective as of January 1, 2020. Specifically, we propose that at least one of the quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must be finalized on the MIPS final list of measures, as described in § 414.1330; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid.

That is, for QP Performance Period 2020 and all future QP Performance Periods, we will treat any measure that is either included in the MIPS final list of measures or has been endorsed by a consensus-based entity as presumptively evidence-based, reliable, and valid. All other measures would need to be independently determined by CMS to be evidence-based, reliable, and valid, in order to be considered MIPS-comparable quality measures.

We believe this revised regulation would better articulate our interpretation of the statute and reflect the MIPS-comparable quality measure standards that are currently met by all Advanced APMs in operation, and that we anticipate would be met by those under development. Additionally, this clarification is intended to align with our parallel proposal for the Other Payer Advanced APM criteria, and maintain consistency between the Advanced APM and Other Payer Advanced APM criteria. We believe this proposal will better align our regulations and inform stakeholders, particularly eligible clinicians or APM Entities who may be participating in both Advanced APMs and Other Payer Advanced APMs in CY 2019, of the applicable quality measure requirements, while also helping non-Medicare payers to continue developing payment arrangements that meet the quality measure criterion to be an Other Payer Advanced APM as discussed at 82 FR 53847.

We seek comment on this proposal.

(c) Outcome Measures: Evidence-Based, Reliable, and Valid

In § 414.1415(b)(3), we generally require that the measures upon which an Advanced APM bases payment must include at least one outcome measure, but specify that this requirement does not apply if CMS determines that there are no available or applicable outcome measures in the MIPS quality measure lists for the Advanced APM's first QP

Performance Period. We note that the current regulation does not require that the outcome measure be evidence-based, reliable, and valid. While it was our general expectation when crafting the CY 2017 Quality Payment Program final rule that outcome measures would meet this standard, we did not explicitly include this requirement.

We are proposing to modify § 414.1415(b)(3) to explicitly require that an outcome measure must be evidence-based, reliable, and valid (unless, as specified in the current regulation, there is no available or applicable outcome measure). This proposal would have an effective date of January 1, 2020, and would specifically require that at least one outcome measure for which measure results are included as a factor when determining payment to participants under the terms of the APM for purposes of paragraph (b)(1) must also be a MIPS-comparable quality measure. This is intended to align with our parallel proposal for the Other Payer Advanced APM criteria. We believe this proposal will better align our regulations and inform stakeholders, particularly eligible clinicians or APM Entities who may be participating in both Advanced APMs and Other Payer Advanced APMs in CY 2019, of the originally intended applicable outcomes measure requirements for APMs to be deemed Advanced APMs and for payment arrangements to be deemed Other Payer Advanced APMs, while also helping non-Medicare payers to continue developing payment arrangements that meet the outcomes measure requirement to be an Other Payer Advanced APM.

As such, we propose to modify § 414.1415(b)(3) (as similarly proposed in the General Quality Measures: Evidence-Based, Reliable, and Valid section III.H.4.d.(3)(b) of this proposed rule), so that at least one outcome measure used for purposes of § 414.1415(b)(1) must also be:

- Finalized on the MIPS final list of measures, as described in § 414.1330;
- Endorsed by a consensus-based entity; or
- Determined by CMS to be evidence-based, reliable, and valid.

As for the proposed requirement for an evidence-based, reliable, and valid quality measure, as we discuss in section III.H.4.d.(3)(b) of this proposed rule, we propose to treat any measure that is either included in the MIPS final list of measures or has been endorsed by a consensus-based entity as presumptively evidence-based, reliable, and valid. All other measures would need to be determined by CMS to be evidence-based, reliable, and valid.

We believe this modification to our regulation would increase the likelihood that the inclusion of quality measures in Advanced APMs will lead to improvements in the quality of care and resulting patient outcomes. Because an Advanced APM is required to base payment on an outcome measure, (unless an applicable outcome measure is not available), participants in Advanced APMs may have powerful financial incentives to modify their behaviors to improve their performance on this measure. Outcome measures that are not evidence-based, reliable, and valid may encourage adverse patient selection, or create other unintended or perverse incentives for model participants. As such, we believe it is important that the outcome measures on which results are included as a factor when determining payment under the APM must be evidence-based, reliable, and valid. We note that these proposed changes would not change the status of any APMs in our current portfolio of Advanced APMs.

We seek comment on this proposal.

(4) Bearing Financial Risk for Monetary Losses

(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized the amount of the generally applicable revenue-based nominal amount standard at 8 percent for the first two QP Performance Periods only, and we sought comment on what the revenue-based nominal amount standard should be for the third and subsequent QP Performance Periods. Specifically, we sought comment on: (1) Setting the revenue-based standard for 2019 and later at up to 15 percent of revenue; or (2) setting the revenue-based standard at 10 percent so long as risk is at least equal to 1.5 percent of expected expenditures for which an APM Entity is responsible under an APM (81 FR 77427).

In the CY 2018 Quality Payment Program final rule, we finalized our proposal to maintain the generally applicable revenue-based nominal amount standard at 8 percent for the 2019 and 2020 QP Performance Periods at § 414.1415(c)(3)(i)(A). We also specified that the standard is based on the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities. We stated that we would address the nominal amount standard for QP Performance Periods after 2020 in future rulemaking (82 FR 53838).

(b) Generally Applicable Nominal Amount Standard

We propose to amend our regulation at § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

We continue to believe that 8 percent of Medicare Parts A and B revenues of all providers and suppliers in participating APM Entities generally represents an appropriate standard for more than a nominal amount of financial risk at this time. We also believe that maintaining a consistent standard for several more years will help APM Entities to plan for multi-year Advanced APM participation. We further believe that maintaining a consistent standard will allow us to evaluate how APM Entities succeed within these parameters over the applicable timeframe.

We seek comment on the proposal to maintain the 8 percent nominal amount standard for QP Performance Periods through 2024.

We also seek comment on whether, as APM entities and participating eligible clinicians grow more comfortable with assuming risk, we should consider increasing the nominal amount standard. Specifically, we request comments on whether we should consider raising the revenue-based nominal amount standard to 10 percent, and the expenditure-based nominal amount standard to 4 percent starting for QP Performance Periods in 2025 and later.

(5) Summary of Proposals

In this section, we are proposing the following policies:

- *Use of CEHRT:*

++ We are proposing to revise our regulation at § 414.1415(a)(i) to specify that an Advanced APM must require at least 75 percent of eligible clinicians in each APM Entity use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals.

- *MIPS-Comparable Quality Measures*

++ We are proposing to revise our regulation to clarify at § 414.1415(b)(2), effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity;

or determined by CMS to be evidenced-based, reliable, and valid.

++ We are also proposing to revise our regulation at § 414.1415(b)(3), effective January 1, 2020, to provide that at least one outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM must either be finalized on the MIPS final list of measures as described in § 414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

- *Bearing Financial Risk for Monetary Losses:* We propose to amend our regulation at § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

e. Qualifying APM Participant (QP) and Partial QP Determinations

(1) Overview

We finalized policies relating to QP and Partial QP determinations in the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77450).

(2) QP Performance Period

In the CY 2017 Quality Payment Program final rule, we finalized for the timing of QP determinations that a QP Performance Period runs from January 1 through August 31 of the calendar year that is 2 years prior to the payment year (81 FR 77446–77447). During that QP Performance Period, we will make QP determinations at three separate snapshot dates (March 31, June 30, and August 31), each of which would be a final determination for the eligible clinicians who are determined to be QPs. The QP Performance Period and the three separate QP determinations apply similarly for both the group of eligible clinicians on a Participation List and the individual eligible clinicians on an Affiliated Practitioner List.

We also finalized that for each of the three QP determinations, we will allow for claims run-out for 3 months, or 90 days, before calculating the Threshold Scores so that QP determinations will be completed approximately 4 months after each snapshot date. As a result, the last of these three QP determinations is complete on or around January 1 of the subsequent calendar year, which is the year immediately prior to the MIPS payment year. For most MIPS data submission types, January 1 of the subsequent calendar year is also the beginning of the MIPS data submission

period. This way, eligible clinicians know of their QP status prior to or near the beginning of the MIPS data submission period and know whether they should report any performance period data to MIPS for the applicable MIPS payment year.

Upon further consideration and based on our experience implementing the program to date, we believe providing eligible clinicians notification of their QP status more quickly after each of the three QP determination snapshot dates, and prior to the beginning of the MIPS data submission period after the last determination, will potentially reduce burden for eligible clinicians and APM Entities while improving their overall experience participating in the program.

Therefore, we propose that for each of the three QP determination dates, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations will be completed approximately 3 months after the end of that determination time period. We note that this proposal does not affect the QP Performance Period per se, but rather the date by which claims for services furnished during the QP Performance Period would need to be processed in order for those services to be included in calculating the Threshold Scores. To the extent that claims are used for calculating the Threshold Scores, such claims would have to be processed by no later than 60 days after each of the three QP determination dates, in order for information on the claims to be included in our calculations. Based on our analysis of Medicare Part B claims for 2014, we found that there is only a 0.5 percent difference in claims processing completeness when using 60 days rather than 90 days.

We seek comment on this proposal.

(3) Partial QP Election To Report to MIPS

(a) Overview

Section 1848(q)(1)(C)(ii)(II) of the Act excludes from the definition of MIPS eligible clinician an eligible clinician who is a Partial QP for a year and who does not report on applicable measures and activities as required under MIPS for the year. However, under section 1848(q)(1)(C)(vii) of the Act, an eligible clinician who is a Partial QP for a year and reports on applicable measures and activities as required under the MIPS is considered to be a MIPS eligible clinician for the year.

In the CY 2017 Quality Payment Program final rule, we finalized that following a determination that eligible

clinicians in an APM Entity group in an Advanced APM are Partial QPs for a year, the APM Entity will make an election whether to report on applicable measures and activities as required under MIPS. If the APM Entity elects to report to MIPS, all eligible clinicians in the APM Entity would be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the APM Entity elects not to report, all eligible clinicians in the APM Entity group will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year (81 FR 77449).

We also finalized that in cases where the Partial QP determination is made at the individual eligible clinician level, if the individual eligible clinician is determined to be a Partial QP, the eligible clinician will make the election whether to report on applicable measures and activities as required under MIPS and, as a result, be subject to the MIPS reporting requirements and payment adjustment (81 FR 77449). If the individual eligible clinician elects to report to MIPS, he or she would be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the individual eligible elects not to report to MIPS, he or she will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year. We note that QP determinations are made at the individual eligible clinician level when the clinician is identified as participating in an Advanced APM on an Affiliated Practitioner List rather than a Participation List, or when an eligible clinician is in more than one APM Entity group in one or more Advanced APMs, and does not achieve QP status as part of any single APM Entity group (see § 414.1425(b)(2) and (c)(4) our regulations).

We also clarified how we consider the absence of an explicit election to report to MIPS or to be excluded from MIPS. We finalized that for situations in which the APM Entity is responsible for making the decision on behalf of all eligible clinicians in the APM Entity group, the group of Partial QPs will not be considered MIPS eligible clinicians unless the APM Entity opts the group into MIPS participation, so that no actions other than the APM Entity's election for the group to participate in MIPS would result in MIPS participation (81 FR 77449).

For eligible clinicians who are determined to be Partial QPs individually, we finalized that we will use the eligible clinician's actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS in

the absence of an explicit election. Therefore, if an eligible clinician who is individually determined to be a Partial QP submits information to MIPS (not including information automatically populated or calculated by CMS on the Partial QP's behalf), we will consider the Partial QP to have reported, and thus to be participating in MIPS. Likewise, if such an individual does not take any action to submit information to MIPS, we will consider the Partial QP to have elected to be excluded from MIPS (81 FR 77449).

(b) Alignment of Partial QP Election Policies

Upon further consideration and based on our experience implementing the program to date, we believe there is value in aligning our Partial QP election policies across all eligible clinicians, whether they achieved Partial QP status as a part of an APM Entity or as an individual. We believe this approach will allow for greater simplicity and clarity for stakeholders.

Therefore, we propose that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician elects to not report to MIPS, they will not be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician does not make any election, they will not be subject to the MIPS reporting requirements and payment adjustment.

We believe that this default minimizes the possibility of unexpected participation in MIPS. Currently, eligible clinicians who are determined to be Partial QPs individually could inadvertently be subject to the MIPS reporting requirements and payment adjustment based on reporting behavior that is not fully within their control. We also believe this approach will minimize the risk that an individual eligible clinician, particularly one whose NPI is associated with multiple billing TINs, inadvertently will be subject to MIPS when that was not that clinician's preference or expectation. We believe it is important that we act in accordance with the preference of an eligible clinician who is individually determined to be a Partial QP with regards to whether they wish to be excluded from MIPS based on the QP status they were able to achieve, regardless of the MIPS reporting election decisions of other TINs with

which that Partial QP's NPI is associated.

Furthermore, this proposal creates alignment in the implementation of our Partial QP election policy for eligible clinicians who are determined to be Partial QPs individually and for eligible clinicians who are determined to be Partial QPs at the APM Entity level. Currently, for eligible clinicians who are determined to be Partial QPs at the APM Entity level, that group of Partial QPs will not be considered MIPS eligible clinicians in the absence of an explicit election to report to MIPS or to be excluded from MIPS by their APM Entity (81 FR 77449). This proposal would establish the same default in the absence of an explicit election to report to MIPS or to be excluded from MIPS for eligible clinicians who are determined to be Partial QPs individually, so that no actions other than the individual Partial QP's affirmative election to participate in MIPS would result in MIPS participation.

We note that this policy change would only affect situations where the Partial QP makes no election to either report to MIPS or to be excluded from the MIPS reporting requirements and payment adjustment. Under our proposed policy, all Partial QPs retain the full right to affirmatively decide through the election process whether or not to be subject to the MIPS reporting requirements and payment adjustment; whereas, if the Partial QP does not make any election, they will not be subject to the MIPS reporting requirements and payment adjustment.

We seek comment on this proposal.

(4) Summary of Proposals

In this section, we are proposing the following policies:

We propose that for each of the three QP determinations, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations will be completed approximately 3 months after the end of that determination time period.

We also propose that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician elects not to report, they will be excluded from the MIPS reporting requirements and payment adjustment. In the absence of an explicit election to report to MIPS,

the eligible clinician will be excluded from the MIPS reporting requirements and payment adjustment. This means that no actions other than the eligible clinician's affirmative election to participate in MIPS would result in that eligible clinician becoming subject to the MIPS reporting requirements and payment adjustment.

g. All-Payer Combination Option

(1) Overview

Section 1833(z)(2)(B)(ii) of the Act requires that beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the Combination All-Payer and Medicare Payment Threshold Option, which we refer to as the All-Payer Combination Option. In the CY 2017 Quality Payment Program final rule, we finalized our overall approach to the All-Payer Combination Option (81

FR 77459). The Medicare Option focuses on participation in Advanced APMs, and we make QP determinations under this option based on Medicare Part B covered professional services attributable to services furnished through an APM Entity. The All-Payer Combination Option does not replace or supersede the Medicare Option; instead, it will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs. We finalized that beginning in payment year 2021, we will conduct QP determinations sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77438). The All-Payer Combination

Option encourages eligible clinicians to participate in payment arrangements with payers other than Medicare that have payment designs that satisfy the Other Payer Advanced APM criteria. It also encourages sustained participation in Advanced APMs across multiple payers.

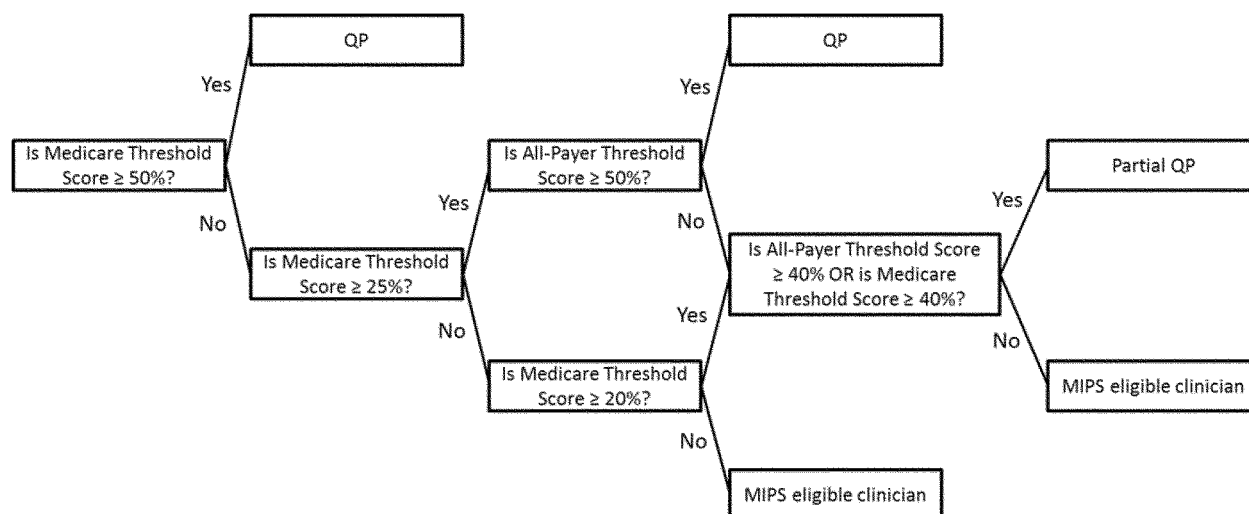
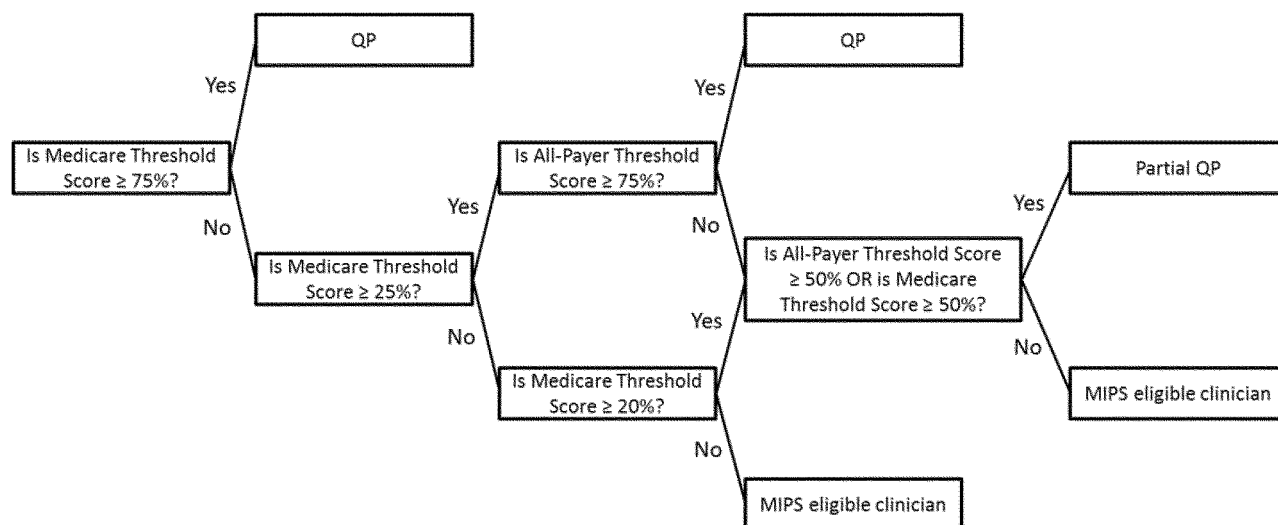
We finalized that the QP determinations under the All-Payer Combination Option are based on payment amounts or patient counts as illustrated in Tables 36 and 37, and Figures 1 and 2 of the CY 2017 Quality Payment Program final rule (81 FR 77460 through 77461). We also finalized that, in making QP determinations with respect to an eligible clinician, we will use the Threshold Score that is most advantageous to the eligible clinician toward achieving QP status, or if QP status is not achieved, Partial QP status, for the year (81 FR 77475).

TABLE 57—QP PAYMENT AMOUNT THRESHOLDS—ALL-PAYER COMBINATION OPTION

Payment year	2019	2020	2021 (%)	2022 (%)	2023 and later (%)
QP Payment Amount Threshold:					
Medicare Minimum	N/A	N/A	25	25	25
Total	50	50	75
Partial QP Payment Amount Threshold:					
Medicare Minimum	N/A	N/A	20	20	20
Total	40	40	50

TABLE 58—QP PATIENT COUNT THRESHOLDS—ALL-PAYER COMBINATION OPTION

Payment year	2019	2020	2021 (%)	2022 (%)	2023 and later (%)
QP Patient Count Threshold:					
Medicare Minimum	N/A	N/A	20	20	20
Total	35	35	50
Partial QP Patient Count Threshold:					
Medicare Minimum	N/A	N/A	10	10	10
Total	25	25	35

FIGURE 1: QP Determination Tree, Payment Years 2021-2022**FIGURE 2: QP Determination Tree, Payment Years 2023 and Later****BILLING CODE 4120-01-C**

Unlike the Medicare Option, where we have access to all of the information necessary to determine whether an APM meets the criteria to be an Advanced APM, we cannot determine whether an other payer arrangement meets the criteria to be an Other Payer Advanced APM without receiving information about the payment arrangement from an external source. Similarly, we do not have the necessary payment amount and patient count information to determine under the All-Payer Combination Option whether an eligible clinician meets the payment amount or patient

count threshold to be a QP without receiving certain information from an external source.

In the CY 2018 Quality Payment Program final rule, we established additional policies to implement the All-Payer Combination Option and finalized certain modifications to our previously finalized policies (82 FR 53844 through 53890). A detailed summary of those policies can be found at 82 FR 53874 through 53876 and 53890 through 53891. In relevant part, we finalized the following:

Payer Initiated Process

- We finalized at § 414.1445(a) and (b)(1) that certain other payers, including payers with payment arrangements authorized under Title XIX (the Medicaid statute), Medicare Health Plan payment arrangements, and payers with payment arrangements aligned with a CMS Multi-Payer Model, can request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2019 QP Performance Period and each year thereafter. We finalized that remaining other payers, including

commercial and other private payers, could request that we determine whether other payer arrangements are Other Payer Advanced APMs starting in 2019 prior to the 2020 QP Performance Period, and annually each year thereafter. We generally refer to this process as the Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process), and we finalized that the Payer Initiated Process would generally involve the same steps for each payer type for each QP Performance Period. If a payer uses the same other payer arrangement in other commercial lines of business, we finalized our proposal to allow the payer to concurrently request that we determine whether those other payer arrangements are Other Payer Advanced APMs as well. This policy is relevant only to the initial year of Payer Initiated Other Payer Advanced APM determinations for which these submissions can be made only by payers with arrangements under Title XIX, Medicare Health Plans, or arrangements aligned with CMS multi-payer models.

Eligible Clinician Initiated Process

- We finalized at § 414.1445(a) and (b)(2) that, through the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements would have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs. The Eligible Clinician Initiated Process can be used to submit requests for determinations before the beginning of a QP Performance Period for other payer arrangements authorized under Title XIX. The Eligible Clinician Initiated Process is available for the 2019 QP Performance Period and each year thereafter.

Submission of Information for Other Payer Advanced APM Determinations

- We finalized that, for each other payer arrangement for which a payer requests us to make an Other Payer Advanced APM determination, the payer must complete and submit the Payer Initiated Submission Form by the relevant Submission Deadline.
- We finalized that, for each other payer arrangement for which an APM Entity or eligible clinician requests us to make an Other Payer Advanced APM determination, the APM Entity or eligible clinician must complete and submit the Eligible Clinician Initiated Submission Form by the relevant Submission Deadline.
- We removed the requirement, previously established at

§ 414.1445(b)(3), that payers must attest to the accuracy of information submitted by eligible clinicians, and we also removed the related attestation requirement at § 414.1460(c). Instead, we finalized an additional requirement at § 414.1445(d) that an APM Entity or eligible clinician that submits information under § 414.1445(c) must certify that, to the best of its knowledge, the information it submits to us is true, accurate, and complete.

QP Determinations Under the All-Payer Combination Option

- We finalized at § 414.1440(e) that eligible clinicians may request that we make QP determinations at the individual eligible clinician level and that APM Entities may request that we make QP determinations at the APM Entity level.
- We finalized at § 414.1440(d)(1) that we will make QP determinations under the All-Payer Combination Option based on eligible clinicians' participation in Advanced APMs and Other Payer Advanced APMs for three time periods of the QP Performance Period: January 1 through March 31; January 1 through June 30; and January 1 through August 31. We finalized that we will use patient or payment data for the same time periods to calculate both the Medicare and the other payer portion of the Threshold Score calculation under the All-Payer Combination Option.
- We finalized at § 414.1440(e)(4) that, to request a QP determination under the All-Payer Combination Option, APM Entities or eligible clinicians must submit all of the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years prior to the payment year, which we refer to as the QP Determination Submission Deadline.

In this section of the proposed rule, we address policies within the following topics: Other Payer Advanced APM Criteria; Other Payer Advanced APM determinations; and Calculation of the All-Payer Combination Option Threshold Scores and QP Determinations.

(2) Other Payer Advanced APM Criteria

(a) Overview

In general, our goal is to align the Advanced APM criteria under the Medicare Option and the Other Payer Advanced APM criteria under the All-Payer Combination Option as permitted by statute and as feasible and appropriate. We believe this alignment would help simplify the Quality

Payment Program and encourage participation in Other Payer Advanced APMs (82 FR 53847).

(b) Investment Payments

Some stakeholders have requested that we take into account “business risk” costs such as IT, personnel, and other administrative costs associated with APM Entities' participation in Other Payer Advanced APMs when implementing the financial risk standard. We are not proposing to modify our financial risk standard in response to this suggestion, and note that financial risk in the context of Other Payer Advanced APMs is defined both in the Act (at section 1833(z)(2)(B)(iii)(II)(cc) for payment years 2021 and 2022, and section 1833(z)(3)(B)(iii)(II)(cc) for subsequent years) and our regulations at § 414.1420(d) so as to require that APM Entities in the payment arrangement must assume financial risk when actual expenditures exceed expected expenditures. However, we note that a payment arrangement with an other payer, like some APMs, can be structured so that the APM provides an investment payment to the participating APM Entities to assist with the practice transformation that may be required for participation in the payment arrangement. This investment payment could be structured in various ways; for example, it could be structured similarly to the Medicare ACO Investment model under, which expected shared savings payment were pre-paid to encourage new ACOs to form in rural and underserved areas and to assist existing ACOs in meeting certain criteria; or it could be structured so that the payment is made specifically to encourage participating APM Entities to continue to make staffing, infrastructure, and operations investments as a means of practice transformation; or it could have a different structure entirely.

(c) Use of CEHRT

(i) Overview

In the CY 2017 Quality Payment Program final rule, we finalized that to be an Other Payer Advanced APM, the other payer arrangement must require at least 50 percent of participating eligible clinicians in each APM Entity, or each hospital if hospitals are the APM Entities, to use CEHRT to document and communicate clinical care (81 FR 77465). This CEHRT use criterion directly paralleled the criterion established for Advanced APMs in § 414.1415(a)(1)(i).

In the CY 2018 Quality Payment Program final rule, we finalized that we would presume that an other payer arrangement meets the 50 percent CEHRT use criterion if we receive information and documentation from the eligible clinician through the Eligible Clinician Initiated Process showing that the other payer arrangement requires the requesting eligible clinician to use CEHRT to document and communicate clinical care (see § 414.1445(c)(2)). We sought comment on whether we should consider revising the 50 percent CEHRT use requirement in future years, and if so what standard we should use in its place (82 FR 53874).

(ii) Increasing the CEHRT Use Criterion for Other Payer Advanced APMs

We are proposing to change the current CEHRT use criterion for Other Payer Advanced APMs so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each APM Entity to use CEHRT.

According to data collected by ONC, since the CY 2017 Quality Payment Program final rule was published, EHR adoption has been widespread, and we want to encourage continued adoption. Additionally, in response to the CY 2017 Quality Payment Program proposed rule stakeholders encouraged us to raise the CEHRT threshold to 75 percent in previous comment solicitations (see 81 FR 77411). We believe that this proposed change aligns with our proposed change in the Advanced APM section, wherein we also propose raising the CEHRT use criterion to 75 percent. We believe that this proposed change aligns with the increased adoption of CEHRT among providers and suppliers that is already happening, and would encourage further CEHRT adoption. Further, we believe the January 1, 2020, adoption date would give stakeholders sufficient time to make the necessary changes for the adoption of this requirement; specifically, this will allow other payers additional time to address the proposed increase to the CEHRT use criterion.

We seek comment on this proposal.

(iii) Evidence of CEHRT Use

In the CY 2017 Quality Payment Program final rule, we adopted a CEHRT use criterion for Other Payer Advanced APMs that directly paralleled the CEHRT use criterion for Advanced APMs wherein Other Payer Advanced APMs must require at least 50 percent of eligible clinicians in each

participating APM Entity, or each hospital if hospitals are the APM Entities, to use CEHRT to document and communicate clinical care.

We have since heard from payers and other stakeholders that CEHRT is often used under other payer arrangements even if it is not expressly required under the payment arrangement. Because CEHRT use is increasingly common among eligible clinicians, payers may not believe it is necessary to specifically require the use of CEHRT under the terms of an Other Payer payment arrangement.

We also note that the statutory CEHRT use requirement for Other Payer Advanced APMs differs from the comparable standard for Advanced APMs. The statutory CEHRT use criterion for Advanced APMs under section 1833(z)(3)(D)(i)(I) of the Act specifies that the APM must require participants in such model to use CEHRT. This differs from section 1833(z)(2)(B)(iii)(II)(bb) of the Act (for payment years 2021 and 2022) and section 1833(z)(2)(C)(iii)(II)(bb) of the Act (for payment years beginning in 2023), which specify that Other Payer Advanced APMs are payment arrangements in which “CEHRT is used.”

Given this, we believe our current policy may needlessly exclude certain existing payment arrangements that could meet the statutory requirements for Other Payer Advanced APMs—including some where the majority of eligible clinicians use CEHRT, even if they are not explicitly required to do so under the terms of their payment arrangements. Accordingly, we are proposing to modify our current policy to offer additional flexibility that we believe would match more closely with both the statute and current practices among other payers.

We are proposing that a payer or eligible clinician must provide documentation to CMS that CEHRT is used to document and communicate clinical care under the payment arrangement by at least 50 percent of eligible clinicians in 2019, and 75 percent of the eligible clinicians in 2020 and beyond, whether or not such CEHRT use is explicitly required under the terms of the payment arrangement. We are specifically proposing to modify the regulation at § 414.1420(b) to specify that to be an Other Payer Advanced APM, CEHRT must be used by at least 50 percent of eligible clinicians participating in the arrangement in 2019 (or, beginning in 2020, 75 percent) of such eligible clinicians).

While a payer that requests an Other Payer Advanced APM determination for

a payment arrangement could continue to meet the proposed CEHRT use requirement by demonstrating that CEHRT use is required of at least 50 percent of eligible clinicians in 2019, (or, beginning in 2020, of at least 75 percent of eligible clinicians), under the terms of the payment arrangement, the payer and eligible clinicians also could meet the criterion by documenting CEHRT use among participating APM entities. Documentation could come from a variety of sources. For example, the level of CEHRT use in a particular State Medicaid program could be demonstrated by presenting data from the ONC showing the CEHRT adoption rate for all physicians in that state along with state data on the percentage of physicians that participate in the State Medicaid program. Similarly, commercial payers could document that CEHRT adoption rates within their networks meet or exceed the relevant CEHRT use percentage for the year. This is not an exhaustive list of ways that other payers could document CEHRT use under their payment arrangements, but suggests some of the possible ways to do so. With regard to submissions from eligible clinicians, similar sources of information on CEHRT adoption could be used, such as data from the State Medicaid Agency or the local health information exchange. To determine whether the CEHRT use criterion is met, we are willing to consider data from a payer or eligible clinician. Based on our conversations with other payers regarding their payment arrangements, including States with regard to their Medicaid payer arrangements, Medicare Advantage Organizations with regard to their Medicare Advantage arrangements, and commercial payers, we believe this modification would offer additional flexibility and potentially match more closely with the current commercial payer landscape, as CEHRT is likely often used under other payer arrangements even if it is not expressly required in the agreement.

We seek comment on this proposal.

(d) MIPS Comparable Quality Measures

(i) Overview

In the CY 2017 Quality Payment Program final rule, we explained that one of the criteria for a payment arrangement to be an Other Payer Advanced APM is that it must apply quality measures comparable to those under the MIPS quality performance category (81 FR 77465).

In the CY 2017 Quality Payment Program proposed rule, we proposed that to be an Other Payer Advanced

APM, a payment arrangement must have quality measures that are evidence-based, reliable, and valid; and that at least one measure must be an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. We generally refer to these measures in the remainder of this discussion as “MIPS-comparable quality measures.” We did not specify that the outcome measure is required to be evidence-based, reliable, and valid (81 FR 77466). We finalized these policies in the CY 2017 Quality Payment Program final rule and codified them in the regulation at § 414.1420(c).

(ii) General Quality Measures: Evidence-Based, Reliable, and Valid

In the CY 2017 Quality Payment Program final rule, we codified at § 414.1420(c)(2) that at least one of the quality measures used in the payment arrangement with an APM Entity must have an evidence-based focus, be reliable, and valid, and meet at least one of the following criteria:

- Used in the MIPS quality performance category as described in § 414.1330;
- Endorsed by a consensus-based entity;
- Developed under section 1848(s) of the Act;
- Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or
- Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid.

It has come to our attention that, as with the comparable policy for Advanced APMs as discussed at 81 FR 28302, some have read the regulation at § 414.1420(c)(2) to mean that measures on the MIPS final list or submitted in response to the MIPS Call for Quality Measures necessarily are MIPS-comparable quality measures, even if they have not been determined to be evidence-based, reliable, and valid. We did not intend to imply that any measure that was merely submitted in response to the annual call for quality measures or developed using Quality Payment Program funding would automatically qualify as MIPS-comparable even if the measure was never endorsed by a consensus-based entity, adopted under MIPS, or otherwise determined to be evidence-based, reliable, and valid. While we believe such measures may be evidence-based, reliable, and valid, we did not intend consider them so for purposes of § 414.1420(c)(2) without independent verification by a consensus-based entity, or based on our own assessment and determination, that they are evidence-

based, reliable, and valid. We further believe the same principle applies to QCDR measures. If QCDR measures are endorsed by a consensus-based entity they are presumptively considered MIPS-comparable quality measures for purposes of § 414.1420(c)(2); otherwise we would have needed independent verification, or to make our own assessment and determination, that the measures are evidence-based, reliable, and valid before considering them to be MIPS-comparable (see 81 FR 77415 through 77417).

Because of the potential ambiguity in the existing definition and out of an abundance of caution in order to avoid any adverse impact on APM entities, eligible clinicians or other stakeholders, we have used the more permissive interpretation of the text, wherein measures developed under section 1848(s) of the Act and submitted in response to the MIPS Call for Quality Measures will meet the quality criterion in implementing the program thus far, and intend to use this interpretation for the 2019 QP Performance Period. Recognizing that APMs and other payer arrangements that we might consider for Advanced APM and Other Payer Advanced APM determinations are well into development for 2019, we would use this interpretation until our new proposal described below is effective on January 1, 2020.

Therefore, at § 414.1420(c)(2), we are proposing, effective as of January 1, 2020, that at least one of the quality measures used in the payment arrangement with an APM Entity must meet at least one of the following criteria:

- Finalized on the MIPS final list of measures, as described in § 414.1330;
- Endorsed by a consensus-based entity; or
- Otherwise determined by CMS to be evidence-based, reliable, and valid.

That is, for QP Performance Period 2020 and all future QP Performance Periods, we would treat any measure that is either included in the MIPS final list of measures or has been endorsed by a consensus-based entity as presumptively evidence-based, reliable, and valid. All other measures would need to be independently determined by CMS to be evidence-based, reliable, and valid, in order to be considered MIPS-comparable quality measures.

We believe this revised regulation would better articulate our interpretation of the statute and reflect the MIPS-comparable quality measure standards that are currently met by all Advanced APMs in operation and that we anticipate would be met by those under development. Additionally, this

clarification is intended to align with our parallel proposal for the Advanced APM criteria, and maintain consistency between the Advanced APM and Other Payer Advanced APM criteria. We believe this clarification will better align our regulations and inform stakeholders, particularly eligible clinicians or APM Entities who may be participating in both Advanced APMs and Other Payer Advanced APMs in CY 2019, of the applicable quality measure requirements, while also helping non-Medicare payers to continue developing payment arrangements that meet the quality measure criterion to be an Other Payer Advanced APM as discussed at 82 FR 53847.

(iii) Outcome Measures: Evidence-Based, Reliable, and Valid

In § 414.1420(c)(3), we generally require that, to be an Other Payer Advanced APM, the payment arrangement must use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. We note that the current regulation does not require that the outcome measure be evidence-based, reliable, and valid.

We are proposing to revise § 414.1420(c)(3), to explicitly require that, unless there is no applicable outcome measure on the MIPS quality measure list, at least one outcome measure that applies in the payment arrangement must be evidence-based, reliable, and valid. This proposal would have an effective date of January 1, 2020, and would specifically require that an outcome measure must also be MIPS-comparable. This proposal aligns with the similar proposal for Other Payer Advanced APMs discussed at section III.H.4.d.(2)(d)(ii) of this proposed rule, so that an outcome measure used in the payment arrangement must also be:

- Finalized on the MIPS final list of measures, as described in § 414.1330;
- Endorsed by a consensus-based entity; or
- Determined by CMS to be evidence-based, reliable, and valid.

As with the general requirement for an evidence-based, reliable, and valid quality measure, as we propose to clarify at section III.H.4.d.(2)(d)(ii) of this proposed rule, we would treat any measure that is either included in the MIPS final list of measures or has been endorsed by a consensus-based entity as presumptively evidence-based, reliable, and valid. All other measures would need to be determined by CMS to be evidence-based, reliable, and valid.

We believe this modification to our regulation would increase the likelihood

that Other Payer Advanced APMs use quality measures that will lead to improvements in the quality of care and resulting patient outcomes. Because an Other Payer Advanced APM is required to use an outcome measure unless no one is available, participants in Other Payer Advanced APMs may have powerful financial incentives to modify their behaviors to improve their performance on this measure. Outcome measures that are not evidence-based, reliable, and valid may encourage adverse patient selection, or create other unintended and perverse incentives for model participants. As such, we believe it is important that the outcome measure be evidence-based, reliable, and valid.

We propose to make this change to our regulation effective January 1, 2020. This proposed effective date is intended to provide stakeholders sufficient notice of, and opportunity to respond to, this change in our regulation because the current regulation does not explicitly require that an outcomes measures must be evidence-based, reliable, and valid and, as a result some Other Payer Advanced APMs that were submitted for determination in CY 2018 for the CY 2019 performance year may not include outcomes measures that are evidence-based, reliable, and valid.

We also propose that, for such payment arrangements that are determined to be Other Payer Advanced APMs for the 2019 performance year and did not include an outcome measure that is evidence-based, reliable, and valid, and that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as proposed in section III.H.4.g.(3)(b) of this proposed rule), we would continue to apply the current regulation for purposes of those determinations. Additionally, payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later, will be assessed under the rules of the current regulation meaning they do not need to include an outcome measure that is evidence-based, reliable, and valid to be an Other Payer Advanced APM. For all other payment arrangements the proposed revised regulation would apply beginning in CY 2020.

We believe this is necessary because there may be some Other Payer Advanced APMs that currently do not include outcomes measures that are evidence-based, reliable, and valid because the current regulation does not explicitly require it. In order to provide for an even application of our current

policy and an even transition to the proposed policy, and to avoid any adverse impact on APM entities, eligible clinicians or other stakeholders, we believe it is appropriate to apply the revision to § 414.1420(c)(3) beginning with determinations that occur after 2020 with respect to those payment arrangements noted above. We also note that this exception would apply for only one year for single-year determinations, and only through the earlier of the end of the payment arrangement or 5 years for determinations under multi-year determination process proposed in section III.H.4.g.(3)(b) of this proposed rule. For all payment arrangements starting in 2020, or those initially submitted for Other Payer Advanced APM determinations for the 2021 performance year and later, the payment arrangement would need to use an outcome measure that is evidence-based, reliable, and valid unless there is no applicable outcome measure on the MIPS final quality measure list.

We note that these proposed changes to our regulations would not change the status of any payment arrangements that we have determined to be Other Payer Advanced APMs for 2019, or for the basis for our determinations of Other Payer Advanced APMs in 2019 for 2020.

We believe a January 1, 2020, effective date would give stakeholders sufficient notice of, and opportunity to respond to, this change in our regulation.

(e) Financial Risk for Monetary Losses

(i) Overview

In the CY 2018 Quality Payment Program final rule, we finalized our proposal to add a revenue-based nominal amount standard to the generally applicable nominal amount standard for Other Payer Advanced APMs that is parallel to the generally applicable revenue-based nominal amount standard for Advanced APMs. Specifically, we finalized that an other payer arrangement would meet the total risk component of the proposed nominal risk standard if, under the terms of the other payer arrangement, the total amount that an APM Entity potentially owes the payer or foregoes is equal to at least: For the 2019 and 2020 QP Performance Periods, 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities. This standard is in addition to the previously finalized expenditure-based standard. We explained that a payment arrangement would only need to meet one of the two standards. We would use this standard only for other payer arrangements where financial risk is

expressly defined in terms of revenue in the payment arrangement.

(ii) Generally Applicable Nominal Amount Standard

We propose to amend our regulation at § 414.1420(d)(3)(i) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities for QP Performance Periods 2019 through 2024.

We continue to believe that 8 percent the total combined revenues from the payer of providers and suppliers in participating APM Entities generally represents an appropriate standard for more than a nominal amount of financial risk at this time. We further believe that maintaining a consistent standard between Advanced APMs and Other Payer Advanced APMs will allow us to evaluate how APM Entities succeed within these parameters across payers over the applicable timeframe.

We seek comment on the proposal to maintain the 8 percent nominal amount standard for Other Payer Advanced APMs for QP Performance Periods through 2024.

(3) Determination of Other Payer Advanced APMs

(a) Overview

In the CY 2017 Quality Payment Program final rule, we specified that an APM Entity or eligible clinician must submit, by a date and in a manner determined by us, information necessary to identify whether a given payment arrangement satisfies the Other Payer Advanced APM criteria (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we codified at § 414.1445 the Payer Initiated Other Payer Advanced APM Determination Process and the Eligible Clinician Initiated Other Payer Advanced APM Determination Process pertaining to the determination of Other Payer Advanced APMs, as well as specifying the information required for Other Payer Advanced APM determinations (82 FR 53814 through 53873).

(b) Multi-Year Other Payer Advanced APM Determinations

In the CY 2018 Quality Payment Program final rule, we finalized that Other Payer Advanced APM determinations made in response to requests submitted either through the Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process) or the Eligible Clinician Initiated Other Payer Advanced APM Determination Process

(Eligible Clinician Initiated Process) would be in effect for only one year at a time. We sought additional comment regarding the current duration of payment arrangements and whether creating a multi-year determination process would encourage the creation of more multi-year payment arrangements as opposed to payment arrangements that are for one year only. We also sought comment on what kind of information should be submitted annually after the first year to update an Other Payer Advanced APM determination (82 FR 53869 through 53870).

In response to our request for comments, we received several comments asking that we allow Other Payer Advanced APM determinations to be in effect for more than one year at a time. These commenters suggested that requiring annual determinations is burdensome, particularly because payment arrangements for other payers are often implemented through multi-year contracts.

After consideration of this feedback, we are proposing to maintain the annual submission process with the modifications outlined below for both the Payer Initiated Process and the Eligible Clinician Initiated Process. We propose that beginning with the 2019 and 2020 submission periods for Other Payer Advanced APM determinations for performance year 2020, after the first year that a payer, APM Entity, or eligible clinician (which we refer to as the “requester” in the remainder of this discussion) submits a multi-year payment arrangement that we determine to be an Other Payer Advanced APM for that year, the requester would need to submit information only on any changes to the payment arrangement that are relevant to the Other Payer Advanced APM criteria for each successive year for the remaining duration of the payment arrangement. In the initial submission, the requester would certify as usual that the information provided about the payment arrangement using the Payer Initiated Process or Eligible Clinician Initiated Process, as applicable, is true, accurate, and complete; would authorize CMS to verify the information; and would certify that they would submit revised information in the event of a material change to the payment arrangement. For multi-year payment arrangements, we propose to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated

information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria and, thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Absent the submission by the requester of updated information to reflect changes to the payment arrangement, we would continue to apply the original Other Payer Advanced APM determination for each successive year through the earlier of the end of that multi-year payment arrangement or 5 years.

We believe this proposal aligns with the multi-year payment arrangements between other payers and eligible clinicians. In many cases, details of the payment arrangements may not change over the full duration of the payment arrangement. In other multi-year arrangements, we understand based on public comments that only certain aspects of the arrangement may change over the multi-year agreement, while most elements of the arrangement remain in place throughout the multi-year term of the agreement. However, because we understand that payment arrangements between payers and eligible clinicians can be renewed for multiple multi-year periods, we propose that the multi-year Other Payer Advanced APM determination would remain in effect until the arrangement is terminated or expires, but in no event longer than 5 years. Although we believe multi-year determinations would appropriately take into account multi-year payment arrangements, thereby reducing burden for requesters, we also believe that requiring a periodic full submission of information about a payment arrangement would be prudent, and that a 5-year interval is a reasonable time frame to require such a full submission using the Payer Initiated Process or Eligible Clinician Initiated Process (or other equivalent submission process that is in place at that time).

We believe that our proposal will more accurately reflect the manner and timeline on which payers make changes to payment arrangements. The current policy requiring payers and eligible clinicians to resubmit a comprehensive description of payment arrangements each year even after an Other Payer Advanced APM determination has been made in the previous year, and when the payment arrangements have a term of multiple years and do not change significantly from year to year, may be overly burdensome and unnecessary as it may require the duplicative resubmission of a substantial amount of information each year. Our proposal

would require, for the shorter of the term of the payment arrangement or five years, the submission of information only in the event there are changes in the information the requestor has submitted, and only when those changes are relevant to the Other Payer Advanced APM criteria and our Other Payer Advanced APM determination. We believe that while this would allow us to continue to conduct regular reviews of the payment arrangements to ensure the criteria for Other Payer Advanced APMs are being met, it would greatly reduce the burden on the payers, APM Entities, and eligible clinicians that submit requests for Other Payer Advanced APM determinations for multi-year payment arrangements.

Further, we believe this proposal would simplify the Other Payer Advanced APM determination process and would likely result in more Other Payer Advanced APMs in general, specifically more Other Payer Advanced APMs that are identified for multiple successive years. This, in turn, would make the Quality Payment Program simpler, as well as increase year-to-year consistency, and reliability for clinicians.

We seek comment on this proposal.

(c) Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process)—Remaining Other Payers

In the CY 2018 Quality Payment Program final rule, we finalized that we will allow certain other payers, including payers with payment arrangements authorized under Title XIX, Medicare Health Plan payment arrangements, and payers with payment arrangements aligned with a CMS Multi-Payer Model to use the Payer Initiated Process to request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2019 QP Performance Period and each year thereafter (82 FR 53854). We codified this policy at § 414.1445(b)(1).

We also finalized that the remaining other payers, including commercial and other private payers, may request that we determine whether other payer arrangements are Other Payer Advanced APMs starting prior to the 2020 QP Performance Period and each year thereafter (82 FR 53867).

In this section, we are proposing details regarding the Payer Initiated Process for the remaining other payers that were not among those other payers permitted to use the Payer Initiated Process to submit their arrangements for Other Payer Advanced APM Determinations in 2018 (Remaining

Other Payers). To the extent possible, we are aligning the Payer Initiated Process for remaining other payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.

In the CY 2018 Quality Payment Program final rule, we finalized that the Payer Initiated Process will be voluntary for all payers (82 FR 53855). We note that the Payer Initiated Process will be similarly voluntary for payers that were permitted to submit payment arrangements in 2018 and for remaining other payers starting in 2019.

Guidance and Submission Form: As we have for the other payers included in the Payer Initiated Process (82 FR 53874), we intend to make guidance available regarding the Payer Initiated Process for Remaining Other Payers prior to their first Submission Period, which would occur during 2019. We intend to modify the submission form (which we refer to as the Payer Initiated Submission Form) for use by remaining other payers to request Other Payer

Advanced APM determinations, and to make this Payer Initiated Submission Form available to remaining other payers prior to the first Submission Period. We propose that a Remaining Other Payer would be required to use the Payer Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Payer Initiated Submission Form to include questions that are applicable to all payment arrangements and some questions that are specific to a particular type of payment arrangement, and we intend for it to include a way for payers to attach supporting documentation. We propose that remaining other payers may submit requests for review of multiple other payer arrangements through the Payer Initiated Process, though we would make separate determinations as to each other payer arrangement and a payer would be required to use a separate Payer Initiated Submission Form for each other payer arrangement. Remaining

other payers may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

Submission Period: We propose that the Submission Period for the Payer Initiated Process for use by remaining other payers to request Other Payer Advanced APM determinations would open on January 1 of the calendar year prior to the relevant QP Performance Period for which we would make Other Payer Advanced APM determinations. We proposed that the Submission Deadline is June 1 of the year prior to the QP Performance Period for which we would make the determination.

The proposed timeline for the Payer Initiated Process for Remaining Other Payers as well as the finalized timeline for the Payer Initiated Process for Medicaid and Medicare Health Plans, is summarized in Table 59 alongside the final timeline for the Eligible Clinician Initiated Process.

TABLE 59—PROPOSED OTHER PAYER ADVANCED APM DETERMINATION PROCESS FOR MEDICAID, MEDICARE HEALTH PLANS, AND REMAINING OTHER PAYERS FOR QP PERFORMANCE PERIOD 2020

	Payer initiated process	Date	Eligible clinician (EC) initiated process*	Date
Medicaid	Guidance sent to states, then Submission Period Opens.	January 2019	Guidance made available to ECs, then Submission Period Opens.	September 2019.
	Submission Period Closes	April 2019	Submission Period Closes	November 2019.
	CMS contacts states and posts Other Payer Advanced APM List.	September 2019	CMS contacts ECs and states and posts Other Payer Advanced APM List.	December 2019.
Medicare Health Plans	Guidance made available to Medicare Health Plans, then Submission Period Opens.	April 2019	Guidance made available to ECs, then Submission Period Opens.	September 2020.
	Submission Period Closes	June 2019	Submission Period Closes	November 2020.
	CMS contacts Medicare Health Plans and posts Other Payer Advanced APM List.	September 2019	CMS contacts ECs and Medicare Health Plans and posts Other Payer Advanced APM List.	December 2020.
Remaining Other Payers	Guidance made available to Remaining Other Payers, then Submission Period Opens.	January 2019	Guidance made available to ECs, then Submission Period Opens.	September 2020.
	Submission Period Closes	June 2019	Submission Period Closes	November 2020.
	CMS contacts Remaining Other Payers and posts Other Payer Advanced APM List.	September 2019	CMS contacts ECs and Remaining Other Payers and posts Other Payer Advanced APM List.	December 2020.

* Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

CMS Determination: Upon the timely receipt of a Payer Initiated Submission Form, we would use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We propose that if we find that the Remaining Other Payer has submitted incomplete or inadequate information, we would inform the payer and allow

them to submit additional information no later than 15 business days from the date we inform the payer of the need for additional information. For each other payer arrangement for which the Remaining Other Payer does not submit sufficient information in a timely fashion, we would not make a determination in response to that request submitted via the Payer Initiated

Submission Form. As a result, the other payer arrangement would not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

CMS Notification: We intend to notify Remaining Other Payers of our determination for each request as soon as practicable after the relevant

Submission Deadline. We note that Remaining Other Payers may submit information regarding an other payer arrangement for a subsequent QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS website a list (which we refer to as the Other Payer Advanced APM List) of all other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant QP Performance Period, we intend to post the Other Payer Advanced APMs that we determine through the Payer Initiated Process and Other Payer Advanced APMs under Title XIX that we determine through the Eligible Clinician Initiated Process. After the QP Performance Period, we would update this list to include Other Payer Advanced APMs that we determine based on other requests through the Eligible Clinician Initiated Process. We intend to post the list of other payer arrangements that we determine to be Other Payer Advanced APMs through the Payer Initiated Process prior to the start of the relevant QP Performance Period, and then to update the list to include Other Payer Advanced APMs that we determine based on requests received through the Eligible Clinician Initiated Process.

(d) Payer Initiated Process—CMS Multi-Payer Models

In the CY 2018 Quality Payment Program final rule, we finalized that beginning for the first QP Performance Period under the All-Payer Combination Option, payers with a payment arrangement aligned with a CMS Multi-Payer Model may request that we determine whether that aligned payment arrangement is an Other Payer Advanced APM.

We are proposing to eliminate the Payer Initiated Process and submission form that are specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers we have proposed in section III.H.4.g.(3)(c) of this proposed rule, or through the existing Medicaid or Medicare Health Plan payment arrangement submission process, as applicable.

In the first year of implementing the Payer Initiated Process, we intentionally limited the types of payers that could use the process to Medicaid, Medicare Health Plans, and CMS Multi-Payer Models. We limited the types of other

payers that could use the Payer Initiated Process so as to limit the volume of submissions in our first year of implementation, and chose to include payers that already have a programmatic or contractual relationship with CMS. Payers in the category of CMS Multi-Payer Models may be Medicaid, Medicare Health Plans, or commercial payers who have partnered with CMS in the development of some of our Advanced APMs.

In eliminating the Payer Initiated Process and submission form specifically for CMS Multi-Payer Models, we are not prohibiting any of these payers from submitting payment arrangements to request that CMS make Other Payer Advanced APM determinations. Rather, we are providing a process for them within larger categories of the Payer Initiated Process, whether as commercial payers, or as arrangements under Medicaid or Medicare Health Plans. We note that the policies proposed for the Payer Initiated Process for Remaining Other Payers, including the timeframe, deadlines, and submission form are substantially similar or identical to those policies finalized for Payer Initiated Process for payment arrangements under Medicaid and Medicare Health Plans.

(4) Calculation of All-Payer Combination Option Threshold Scores and QP Determinations

(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized our overall approach to the All-Payer Combination Option (81 FR 77463). Beginning in 2021, in addition to the Medicare Option, an eligible clinician may alternatively become a QP through the All-Payer Combination Option, and an eligible clinician need only meet the QP threshold under one of the two options to be a QP for the payment year (81 FR 77459). We finalized that we will conduct the QP determination sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77459).

In the CY 2017 Quality Payment Program final rule, we finalized that we will calculate Threshold Scores under the Medicare Option through both the payment amount and the patient count methods, compare each Threshold Score to the relevant QP and Partial QP Thresholds, and use the most advantageous scores to make QP determinations (81 FR 77457). We finalized the same approach for the All-Payer Combination Option wherein we will use the most advantageous method

for QP determinations with the data that has been provided (81 FR 77475).

(b) QP Determinations Under the All-Payer Combination Option

In the CY 2018 Quality Payment Program final rule, we finalized that an eligible clinician may request a QP determination at the eligible clinician level, and that an APM Entity may request a QP determination at the APM Entity Level (82 FR 53880 through 53881). In the event that we receive a request for QP determination from an individual eligible clinician and also separately from that individual eligible clinician's APM Entity, we would make a determination at both levels. The eligible clinician could become a QP on the basis of either of the two determinations (82 FR 53881).

We sought comment on whether in future rulemaking we should add a third alternative to allow QP determinations at the TIN level when all clinicians who have reassigned billing rights to the TIN are included in a single APM Entity. In particular, we sought comment on whether submitting information to request QP determinations under the All-Payer Combination Option at the TIN level would more closely align with eligible clinicians' existing billing and recordkeeping practices, and thereby be less burdensome (82 FR 53881).

We received several comments asking that we add a third alternative to allow requests for QP determinations at the TIN level. These commenters remarked that TIN-level requests and determinations would align with how payers often contract with practices (that is, at the TIN level), as well as encourage alignment between TIN-level Medicare and Other Payer Advanced APMs, minimize data reporting burden, and promote team-based care.

After considering these comments, and in the interest of increasing flexibility under the All-Payer Combination Option, we are proposing to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity. This option would therefore be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It would also be available to any other TIN for which all clinicians who have reassigned their billing rights to the TIN are participating in a single APM Entity.

We are proposing that, similar to our existing policies for individual and APM Entity requests for QP determinations under the All-Payer Combination Option, we would assess

QP status based on the most advantageous result for each individual eligible clinician. That is, if we receive any combination of QP determination requests (at the TIN-level, APM Entity level, or individual level) we would make QP assessments at all requested levels and determine QP status on the basis of the QP assessment that is most advantageous to the eligible clinician.

We are proposing to revise our regulations at § 414.1440(d), to add this third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights to the TIN participate in a single APM Entity, and to assess QP status based on the most advantageous result for each eligible clinician.

We are further proposing to allow TIN level requests for QP determinations only in instances where the entire TIN has met the Medicare threshold for the All-Payer Combination Option based on their participation in Advanced APMs, by virtue of their participation in a single Advanced APM entity. This is by definition not the case in scenarios where an eligible clinician meets the Medicare threshold for the All-Payer Combination Option individually, and therefore we would not allow TIN level request for QP determinations in such scenarios.

We believe that adding the third alternative as proposed would provide more flexibility for eligible clinicians to attain QP status and go further toward reflecting the way that payers typically contract with eligible clinicians. We believe that having three possible levels for QP determinations would likely increase the opportunities of eligible clinicians to attain QP status. Further, we believe this proposal would reduce burdens on eligible clinicians who frequently contract, bill, and report data at the TIN level. This reduction in burden may encourage increased participation in Other Payer Advanced APMs.

(c) Use of Individual or APM Entity Group Information for Medicare Payment Amount and Patient Count Calculation Under the All-Payer Combination Option

(i) Flexibility in the Medicare Option and All-Payer Combination Option Threshold Methods

In the CY 2018 Quality Payment Program final rule, we finalized that when we make QP determinations at the individual eligible clinician level, we would use the individual eligible clinician payment amounts and patient counts for the Medicare calculations in

the All-Payer Combination Option. When we make QP determinations at the APM Entity level, we will use APM Entity level payment amounts and patient counts for the Medicare calculations in QP determinations under the All-Payer Combination Option. Eligible clinicians assessed at the individual eligible clinician level under the Medicare Option at § 414.1425(b)(2) will be assessed at the individual eligible clinician level only under the All-Payer Combination Option. We codified these policies at § 414.1440(d)(2) (82 FR 53881).

Based on comments from stakeholders, we believe there may be some remaining confusion on the relationship between the payment amount and patient count thresholds in the context of the All Payer Combination Option. Therefore, we are reiterating our policy that the minimum Medicare threshold needed to qualify for a QP determination for the All-Payer Combination Option may be calculated based on either payment amounts or patient counts (whichever is more favorable to the clinician); and that the All-Payer threshold, which includes Medicare data, may then be calculated based on either payment amounts or patient counts, regardless of which method was used for the initial Medicare threshold calculation and that we would similarly use whichever is more favorable to the clinician. Some have read our regulation at § 414.1440(d)(2) to suggest that consistency is required across the two thresholds requiring eligible clinicians or APM Entities to meet the minimum Medicare threshold needed to qualify for the All-Payer Combination Option and the All-Payer threshold using the same method—either payment amounts or patient counts. Although we did not directly address this specific question in our current regulation or in prior rulemaking, we are clarifying that eligible clinicians or APM Entities can meet the minimum Medicare threshold for the All-Payer Combination Option using one method (whichever is most favorable), and the All-Payer threshold for the All-Payer Combination Option using either the same, or the other method. All data submitted to us for Other Payer Advanced APM determinations and, when applicable, QP determinations using the All-Payer Combination Option will be considered and evaluated; and eligible clinicians (or APM Entities or TINs, as appropriate) may submit all data relating to both the payment amount and patient count methods.

To avoid any potential ambiguity for the future, we are proposing a change to

our regulation at § 414.1440(d) to codify this clarification. We propose to add a new § 414.1440(d)(4) to expressly allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method.

We believe this clarification will encourage the submission of more complete data with All-Payer Combination Option QP determination requests, maximize the number of QPs, and thereby encourage participation by eligible clinicians in Advanced APMs and Other Payer Advanced APMs by always using the calculation method most favorable to the clinician. Further, we believe the codification of this clarification in our regulation would maximize flexibility while reducing potential uncertainty.

(ii) Extending the Medicare Threshold Score Weighting Methodology to TIN Level All-Payer Combination Option Threshold Score Calculations

In the CY 2018 Quality Payment Program final rule, we explained that we recognize that in many cases an individual eligible clinician's Medicare Threshold Scores would likely differ from the corresponding Threshold Scores calculated at the APM Entity group level, which would benefit those eligible clinicians whose individual Threshold Scores would be higher than the group Threshold Scores and disadvantage those eligible clinicians whose individual Threshold Scores are equal to or lower than the group Threshold Scores (82 FR 53881–53882). In situations where eligible clinicians are assessed under the Medicare Option as an APM Entity group, and receive a Medicare Threshold Score at the APM Entity group level, we believe that the Medicare portion of their All-Payer calculation under the All-Payer Combination Option should not be lower than the Medicare Threshold Score that they received by participating in an APM Entity group.

To accomplish this outcome, we finalized a modified weighting methodology. We finalized that when the eligible clinician's Medicare Threshold Score calculated at the individual level would be lower than the one calculated at the APM Entity group level, we would apply a weighting methodology to calculate the Threshold Score for the eligible clinician. This methodology allows us to apply the APM Entity group level Medicare Threshold Score (if higher than the individual eligible clinician

level Medicare Threshold Score), to the eligible clinician, under either the payment amount or patient count method, but weighted to reflect the

individual eligible clinician’s Medicare volume. We multiply the eligible clinician’s APM Entity group Medicare Threshold Score by the total Medicare

payments or patients made to that eligible clinician as follows:

$$\frac{[APM\ Entity\ Medicare\ Threshold\ Score \times Clinician\ Medicare\ Payments\ or\ Patients] + Individual\ Other\ Payer\ Advanced\ APM\ Payments\ or\ Patients}{Individual\ Payments\ or\ Patients\ (All\ Payers\ except\ those\ excluded)}$$

We propose to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level. In this scenario, we believe that the Medicare portion of the TIN’s

All-Payer Combination Option Threshold Score should not be lower than the Medicare Threshold Score that they received by participating in an APM Entity group (82 FR 53881–53882). We note this extension of the weighting methodology would only apply to a TIN when that TIN represents a subset of the eligible clinicians in the APM Entity,

because when the TIN and the APM Entity are the same there is no need for this weighted methodology. We would multiply the TIN’s APM Entity group Medicare Threshold Score by the total Medicare payments or patients for that TIN as follows:

$$\frac{[APM\ Entity\ Medicare\ Threshold\ Score \times TIN\ Medicare\ Payments\ or\ Patients] + TIN\ Other\ Payer\ Advanced\ APM\ Payments\ or\ Patients}{TIN\ Payment\ or\ Patients\ (All\ Payers\ except\ those\ excluded)}$$

As an example of how this weighting methodology would apply under the payment amount method for payment

year 2021, consider the following APM Entity group with two TINs, one of which participates in Other Payer

Advanced APMs and one which does not.

TABLE 60—WEIGHTING METHODOLOGY EXAMPLE—PAYMENT AMOUNT METHOD

	Medicare— advanced APM payments	Medicare— total payments	Other payer— Advanced APM payments	Other payer— total payments
TIN A	\$150	\$200	\$0	\$500
TIN B	150	800	760	1,200
APM Entity	300	1,000		

In this example, the APM Entity group Medicare Threshold Score is \$300/\$1,000, or 30 percent. Eligible Clinicians in TIN A and B would not be QPs under the Medicare Option, but TIN B could request that we make a QP

determination under the All-Payer Combination Option since the APM Entity group exceeded the 25 percent minimum Medicare payment amount threshold under that option.

If we calculate the TIN’s payments on its own without the proposed weighting policy, we would calculate the Threshold Score as follows:

$$\frac{\$150 + \$760}{\$800 + \$1200} = 46\%$$

Because TIN B’s Threshold Score is less than the 50 percent QP Payment Amount Threshold, TIN B would not

meet the QP Threshold based on this result. However, if we apply the weighting methodology, we would

calculate the Threshold Score as follows:

$$\frac{(\frac{\$300}{\$1000} \times \$800) + \$760}{\$800 + \$1,200} = 50\%$$

Based upon this Threshold Score, TIN B would meet the QP Threshold under the All-Payer Combination Option.

We propose to calculate the TIN’s Threshold Scores both on its own and with this weighted methodology, and

then use the most advantageous score when making a QP determination. We believe that, as it does for QP determinations made at the APM Entity level, this approach promotes consistency between the Medicare

Option and the All-Payer Combination Option to the extent possible. Additionally, the proposed application of this weighting approach in the case of a TIN level QP determination would

be consistent with our established policy.

(5) Summary of Proposals

In this section, we propose the following policies:

Other Payer Advanced APM Criteria

- We are proposing to change the CEHRT use criterion so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the percentage of eligible clinicians participating in the other payer arrangement who are using CEHRT must be 75 percent.

- We are proposing to allow payers and eligible clinicians to submit evidence as part of their request for an Other Payer Advanced APM determination that CEHRT is used by the requisite percentage of eligible clinicians participating in the payment arrangement (50 percent for 2019, and 75 percent for 2020 and beyond) to document and communicate clinical care, whether or not CEHRT use is explicitly required under the terms of the payment arrangement.

- We are proposing the following clarification to § 414.1420(c)(2), effective January 1, 2020, to provide that at least one of the quality measures used in the payment arrangement in paragraph (c)(1) of this regulation must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidence-based, reliable, and valid.

- We are proposing to revise § 414.1420(c)(3) to require that, effective January 1, 2020, unless there is no applicable outcome measure on the MIPS quality measure list, an Other Payer Advanced APM must use an outcome measure, that meets the proposed criteria in paragraph (c)(2) of this regulation.

- We are also proposing at § 414.1420(c)(3)(i) that, for payment arrangements determined to be Other Payer Advanced APMs for the 2019 performance year which did not include an outcome measure that is evidence-based, reliable, and valid, that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as proposed in section III.H.4.g.(3)(b) of this proposed rule), we would continue to apply the current regulation for purposes of those determinations. This proposed revision also applies to payment arrangements in existence prior to the 2020 performance

year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later.

Determination of Other Payer Advanced APMs

- We are proposing details regarding the Payer Initiated Process for remaining other payers. To the extent possible, we are aligning the Payer Initiated Process for remaining other payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.

- We are proposing to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers proposed in section III.H.4.g.(3)(c) of this proposed rule, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

Calculation of All-Payer Combination Option Threshold Scores and QP Determinations

- We propose to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who reassigned billing rights under the TIN participate in a single APM Entity. We propose to modify our regulation at § 414.1440(d), by adding this third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing under the TIN participate in a single APM Entity, as well as to assess QP status at the most advantageous level for each eligible clinician.

- We are also clarifying that, in making QP determinations using the All-Payer Combination Option, eligible clinicians may meet the minimum Medicare threshold using one method, and the All-Payer threshold using the same or a different method. We are proposing to codify this clarification by adding § 414.1440(d)(4).

- We propose to extend the weighting methodology that is used to ensure that an eligible clinician does not receive a lower score on the Medicare portion of their all-payer calculation under the All-Payer Combination Option than the Medicare Threshold Score they received at the APM Entity level in order to apply a similar policy to the proposed TIN level Medicare Threshold Scores. We would use this methodology only in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare

Threshold Score at the APM Entity group level.

5. Quality Payment Program Technical Correction: Regulation Text Changes

We are proposing certain technical revisions to our regulations in order to correct several technical errors and to reconcile the text of several of our regulations with the final policies we adopted through notice and comment rulemaking.

We are proposing a technical revision to § 414.1415(b)(1) of our regulations to specify that an Advanced APM must require quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM. The addition of the word “quality” better aligns with section 1833(z)(3)(D) of the Act and with the policy that was finalized in the CY 2017 Quality Payment Program final rule (81 FR 77406), and corrects a clerical error we made in the course of revising the text of § 414.1415(b)(1) for inclusion in the CY 2017 QPP final rule. This proposed revision would not change our current policy for this Advanced APM criterion.

We are also proposing technical revisions to the regulation at § 414.1420(d)(3)(ii)(B). These changes align with the generally applicable nominal amount standard for Other Payer Advanced APMs that was finalized in the CY 2017 Quality Payment Program final rule, and the change to the generally applicable nominal amount standard in the CY 2018 Quality Payment Program final rule where we established a revenue-based nominal amount standard as part of the Other Payer Advanced APM criteria (82 FR 53849–53850). We finalized that a payment arrangement must require APM Entities to bear financial risk for at least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement, and that a payment arrangement’s level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures, and the maximum allowable minimum loss rate must be 4 percent (81 FR 77471). Due to a clerical oversight, we inadvertently published two conflicting provisions in regulation text; at § 414.1420(d)(3)(i), we correctly finalized that a payment arrangement must require APM Entities to bear financial risk for at least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement, and at § 414.1420(d)(3)(ii)(B) we incorrectly finalized that the risk arrangement must have a total potential risk of at least 4

percent of expected expenditures. We are effectuating this change by removing the Other Payer Advanced APM Criteria, Financial Risk, Generally Applicable Nominal Amount Standard provision at § 414.1420(d)(3)(ii)(B) and consolidating § 414.1420(d)(3)(ii)(A) into § 414.1420(d)(3)(ii).

We are proposing to revise the regulations at §§ 414.1415(c) and 414.1420(d). In the CY 2017 Quality Payment Program final rule, we finalized a capitation standard for the financial risk criterion under the Advanced APM Criteria and the Other Payer Advanced APM Criteria, respectively. We finalized that full capitation arrangements would meet the Advanced APM financial risk criterion and Other Payer Advanced APM financial risk criterion, and would not separately need to meet the generally applicable financial risk standard and generally applicable nominal amount standard in order to satisfy the financial risk criterion for Advanced APMs and Other Payer Advanced APMs (81 FR 77431; 77472). We believe the application of the capitation standard as described by this regulation could be made clearer by revising §§ 414.1415(c) and 414.1420(d) to refer to the full capitation exception that is expressed in paragraphs (c)(6) and (d)(7), respectively.

We are also proposing to revise §§ 414.1415(c)(6) and 414.1420(d)(7). In finalizing §§ 414.1415(c)(6) and 414.1420(d)(7), we specified that a capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services for which payment is made through the APM furnished to a population of beneficiaries, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. This language does not completely reflect our definition of capitation risk arrangements as discussed in preamble at 81 FR 77430 where we state that, “capitation risk arrangements, as defined here, involve full risk for the population of beneficiaries covered by the arrangement, recognizing that it might require no services whatsoever or could require exponentially more services than were expected in calculating the capitation rate. . . . [a] capitation risk arrangement adheres to the idea of a global budget for all items and services to a population of beneficiaries during a fixed period of time.” We propose to revise these regulations to align the Advanced APM Criteria, Financial Risk, Capitation provision at § 414.1415(c)(6), and the Other Payer Advanced APM

Criteria, Financial Risk, Capitation provision at § 414.1420(d)(7) with the definition of capitation risk arrangements that we expressed in the preamble of the CY 2017 Quality Payment Program final rule at 81 FR 77430–77431.

We are also proposing a technical correction to remove the “; or” and replace it with a “.” at § 414.1420(d)(3)(i) because the paragraph that follows that section does not specify a standard that is necessarily an alternative to the standard under § 414.1420(d)(3)(i), but rather expresses a standard that is independent of the standard under § 414.1420(d)(3)(i). As indicated in the CY 2018 Quality Payment Program final rule at 82 FR 53849–53850, where we established a revenue-based nominal amount standard for Other Payer Advanced APMs, in order to meet the generally applicable nominal amount standard under the Other Payer Advanced APM criteria, the total amount that an APM Entity potentially owes the payer or foregoes under a payment arrangement must be equal to at least: for the 2019 and 2020 QP Performance Periods, 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement; or, 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

We are also proposing to amend the regulation at § 414.1440(d)(3) to correct a typographical error by replacing the “are” with “is” in the third clause of the second sentence.

IV. Requests for Information

This section addresses two requests for information (RFIs). Upon reviewing the RFIs, respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; neither RFI constitutes a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. Failing to respond to either RFI will not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor each

RFI announcement for additional information pertaining to the request. Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

Currently, Medicare- and Medicaid-participating providers and suppliers are at varying stages of adoption of health information technology (health IT). Many hospitals have adopted electronic health records (EHRs), and CMS has provided incentive payments to eligible hospitals, critical access hospitals (CAHs), and eligible professionals who have demonstrated meaningful use of certified EHR technology (CEHRT) under the Medicare EHR Incentive Program. As of 2015, 96 percent of Medicare- and Medicaid-participating non-Federal acute care hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care.³⁶ While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many

³⁶ These statistics can be accessed at <https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php>.

localities and regions throughout the Nation.

CMS is firmly committed to the use of certified health IT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). The Office of the National Coordinator for Health Information Technology (ONC) acts as the principal Federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of the Department of Health and Human Services.

In 2015, ONC finalized the 2015 Edition health IT certification criteria (2015 Edition), the most recent criteria for health IT to be certified to under the ONC Health IT Certification Program. The 2015 Edition facilitates greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. CMS requires eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs and eligible clinicians in the Quality Payment Program (QPP) to use EHR technology certified to the 2015 Edition beginning in CY 2019.

In addition, several important initiatives will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information. Section 4003 of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, and amending section 3000 of the Public Health Service Act (42 U.S.C. 300jj), requires HHS to take steps to advance the electronic exchange of health information and interoperability for participating providers and suppliers in various settings across the care continuum. Specifically, Congress directed that ONC “. . . for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally.” In January 2018, ONC

released a draft version of its proposal for the Trusted Exchange Framework and Common Agreement,³⁷ which outlines principles and minimum terms and conditions for trusted exchange to enable interoperability across disparate health information networks (HINs). The Trusted Exchange Framework (TEF) is focused on achieving the following four important outcomes in the long-term:

- Professional care providers, who deliver care across the continuum, can access health information about their patients, regardless of where the patient received care.
- Patients can find all of their health information from across the care continuum, even if they do not remember the name of the professional care provider they saw.
- Professional care providers and health systems, as well as public and private health care organizations and public and private payer organizations accountable for managing benefits and the health of populations, can receive necessary and appropriate information on groups of individuals without having to access one record at a time, allowing them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives.
- The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation that will make health information more accessible and improve EHR usability.

ONC will revise the draft TEF based on public comment and ultimately release a final version of the TEF that will subsequently be available for adoption by HINs and their participants seeking to participate in nationwide health information exchange. The goal for stakeholders that participate in, or serve as, a HIN is to ensure that participants will have the ability to seamlessly share and receive a core set of data from other network participants in accordance with a set of permitted purposes and applicable privacy and security requirements. Broad adoption of this framework and its associated exchange standards is intended to both achieve the outcomes described above while creating an environment more conducive to innovation.

In light of the widespread adoption of EHRs along with the increasing availability of health information

exchange infrastructure predominantly among hospitals, we are interested in hearing from stakeholders on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals, such as: Requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.

On November 3, 2015, we published a proposed rule (80 FR 68126) to implement the provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113–185) and to revise the discharge planning CoP requirements that hospitals (including short-term acute care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals), critical access hospitals (CAHs), and home health agencies (HHAs) would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. However, several of the proposed requirements directly address the issue of communication between providers and between providers and patients, as well as the issue of interoperability:

- Hospitals and CAHs would be required to transfer certain necessary medical information and a copy of the discharge instructions and discharge summary to the patient's practitioner, if the practitioner is known and has been clearly identified;
- Hospitals and CAHs would be required to send certain necessary medical information to the receiving facility/post-acute care providers, at the time of discharge; and
- Hospitals, CAHs, and HHAs would need to comply with the IMPACT Act

³⁷ The draft version of the trusted Exchange Framework may be accessed at <https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>.

requirements that would require hospitals, CAHs, and certain post-acute care providers to use data on quality measures and data on resource use measures to assist patients during the discharge planning process, while taking into account the patient's goals of care and treatment preferences.

We published another proposed rule (81 FR 39448) on June 16, 2016, that updated a number of CoP requirements that hospitals and CAHs would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. One of the proposed hospital CoP revisions in that rule directly addresses the issues of communication between providers and patients, patient access to their medical records, and interoperability. We proposed that patients have the right to access their medical records, upon an oral or written request, in the form and format requested by such patients, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, including current medical records, within a reasonable timeframe. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

We also published a final rule (81 FR 68688) on October 4, 2016, that revised the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. In this rule, we made a number of revisions based on the importance of effective communication between providers during transitions of care, such as transfers and discharges of residents to other facilities or providers, or to home. Among these revisions was a requirement that the transferring LTC facility must provide all necessary information to the resident's receiving provider, whether it is an acute care hospital, an LTCH, a psychiatric facility, another LTC facility, a hospice, a home health agency, or another community-based provider or practitioner (42 CFR 483.15(c)(2)(iii)). We specified that necessary information must include the following:

- Contact information of the practitioner responsible for the care of the resident;
- Resident representative information including contact information;
- Advance directive information;

- Special instructions or precautions for ongoing care;
- The resident's comprehensive care plan goals; and
- All other necessary information, including a copy of the resident's discharge or transfer summary and any other documentation to ensure a safe and effective transition of care.

We note that the discharge summary mentioned above must include reconciliation of the resident's medications, as well as a recapitulation of the resident's stay, a final summary of the resident's status, and the post-discharge plan of care. In addition, in the preamble to the rule, we encouraged LTC facilities to electronically exchange this information if possible and to identify opportunities to streamline the collection and exchange of resident information by using information that the facility is already capturing electronically.

Additionally, we specifically invite stakeholder feedback on the following questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–91), and implementation of relevant policies in the 21st Century Cures Act?
- What would be a reasonable implementation timeframe for compliance with new or revised CMS

CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?

• Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?

• Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?

• Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?

• What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP, including CEHRT hardship or small practices, be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

We would also like to directly address the issue of communication between hospitals (as well as the other providers and suppliers across the continuum of patient care) and their patients and caregivers. MyHealthEData is a government-wide initiative aimed at breaking down barriers that contribute to preventing patients from being able to access and control their medical records. Privacy and security of patient data will be at the center of all CMS

efforts in this area. CMS must protect the confidentiality of patient data, and CMS is completely aligned with the Department of Veterans Affairs (VA), the National Institutes of Health (NIH), ONC, and the rest of the Federal Government, on this objective.

While some Medicare beneficiaries have had, for quite some time, the ability to download their Medicare claims information, in pdf or Excel formats, through the CMS Blue Button platform, the information was provided without any context or other information that would help beneficiaries understand what the data were really telling them. For beneficiaries, their claims information is useless if it is either too hard to obtain or, as was the case with the information provided through previous versions of Blue Button, hard to understand. In an effort to fully contribute to the Federal Government's MyHealthEData initiative, CMS developed and launched the new Blue Button 2.0, which represents a major step toward giving patients meaningful control of their health information in an easy-to-access and understandable way. Blue Button 2.0 is a developer-friendly, standards-based application programming interface (API) that enables Medicare beneficiaries to connect their claims data to secure applications, services, and research programs they trust. The possibilities for better care through Blue Button 2.0 data are exciting, and might include enabling the creation of health dashboards for Medicare beneficiaries to view their health information in a single portal, or allowing beneficiaries to share complete medication lists with their doctors to prevent dangerous drug interactions.

To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. We are particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcome the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other

participating providers and suppliers. We have received stakeholder input through recent CMS Listening Sessions on the need to address health IT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and we would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20548 and 20549) and the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28169 and 79 FR 50146, respectively), we stated that we intend to continue to review and post relevant charge data in a consumer-friendly way, as we previously have done by posting hospital and physician charge information on the CMS website.³⁸ In the FY 2019 IPPS/LTCH PPS proposed rule, we also continued our discussion of the implementation of section 2718(e) of the Public Health Service Act, which aims to improve the transparency of hospital charges. This discussion in the FY 2019 IPPS/LTCH PPS proposed rule continued a discussion we began in the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28169 and 79 FR 50146, respectively). In all of these rules, we noted that section 2718(e) of the Public Health Service Act requires that each hospital operating within the United States, for each year, establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Act. In the FY 2015 IPPS/LTCH PPS proposed and final rules, we reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the Public Health Service Act and provided guidelines for its implementation. We stated that hospitals are required to either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or

their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH PPS proposed rule, we took one step to further improve the public accessibility of charge information. Specifically, effective January 1, 2019, we are updating our guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate.

In general, we encourage all providers and suppliers to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services. We encourage providers and suppliers to update this information at least annually, or more often as appropriate, to reflect current charges.

We are concerned that challenges continue to exist for patients due to insufficient price transparency. Such challenges include patients being surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals and in other settings, and patients being surprised by facility fees, physician fees for emergency department visits, or by fees for providers and suppliers that are part of an episode of care but that were not furnished by the hospital. We also are concerned that, for providers and suppliers that maintain a list of standard charges, the charge data may not be helpful to patients for determining what they are likely to pay for a particular service or facility encounter. In order to promote greater price transparency for patients, we are considering ways to improve the accessibility and usability of current charge information.

We also are considering potential actions that would be appropriate to further our objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients to compare charges for similar services across providers and suppliers, including services that could be offered in more than one setting. Therefore, we are seeking public comment from all providers and suppliers on the following:

- How should we define "standard charges" in various provider and supplier settings? Is there one definition

³⁸ See, for example, Medicare Provider Utilization and Payment Data, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html>.

for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters? Should “standard charges” be defined to mean: Average or median rates for the items on a chargermaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as determined by the provider or supplier based on its billing patterns; or the average discount off the chargermaster, price list or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together? Should “standard charges” be defined and reported for both some measure of the average contracted rate and the chargermaster, price list or charge list? Or is the best measure of a provider’s or supplier’s standard charges its chargermaster, price list or charge list?

- What types of information would be most beneficial to patients, how can providers and suppliers best enable patients to use charge and cost information in their decision-making, and how can CMS and providers and suppliers help third parties create patient-friendly interfaces with these data?

- Should providers and suppliers be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service? How can information on out-of-pocket costs be provided to better support patients’ choice and decision-making? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how co-pays and co-insurance are applied to each service

covered by Medicare? What can be done to better inform patients of their financial obligations? Should providers and suppliers of healthcare services play any role in helping to inform patients of what their out-of-pocket obligations will be?

- Can we require providers and suppliers to provide patients with information on what Medicare pays for a particular service performed by that provider or supplier? If so, what changes would need to be made by providers and suppliers? What burden would be added as a result of such a requirement?

In addition, we are seeking public comment on improving a Medigap patient’s understanding of his or her out-of-pocket costs prior to receiving services, especially with respect to the following particular questions:

- How does Medigap coverage affect patients’ understanding of their out-of-pocket costs before they receive care? What challenges do providers and suppliers face in providing information about out-of-pocket costs to patients with Medigap? What changes can Medicare make to support providers and suppliers that share out-of-pocket cost information with patients that reflects the patient’s Medigap coverage? Who is best situated to provide patients with clear Medigap coverage information on their out-of-pocket costs prior to receipt of care? What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service? What state-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. chapter 35), we

are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A) required issues for the following information collection requirements (ICRs).

A. Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 61 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Private Sector Wages: The adjusted hourly wage is used to calculate the labor costs associated with our proposed requirements.

TABLE 61—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefits and overhead costs (\$/hr)	Adjusted hourly wage (\$/hr)
All Occupations (for Individuals’ Wages)	00–0000	\$24.34	n/a	n/a
Billing and Posting Clerks	43–3021	18.49	\$18.49	\$36.98
Computer Systems Analysts	15–1121	44.59	44.59	89.18
Family and General Practitioner	29–1062	100.27	100.27	200.54
Legal Support Workers, All Other	23–2099	32.67	32.67	65.34
Licensed Practical Nurse (LPN)	29–2061	21.98	21.98	43.96
Medical Secretary	43–6013	17.25	17.25	34.50
Physicians	29–1060	103.22	103.22	206.44
Practice Administrator (Medical and Health Services Managers)	11–9111	53.69	53.69	107.38
Registered Nurse	29–1141	35.36	35.36	70.72

As indicated, we are adjusting our employee hourly wage estimates by a

factor of 100 percent. This is necessarily a rough adjustment, both because fringe

benefits and overhead costs vary significantly from employer to

employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Wages for Individuals: For beneficiaries who elect to complete the CAHPS for MIPS survey, we believe that the burden will be addressed under All Occupations (BLS occupation code 00–0000) at \$24.34/hr since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc. Unlike our private sector adjustment to the respondent hourly wage, we are not adjusting this figure for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding the Clinical Laboratory Fee Schedule (CLFS) (Section III.A. of This Proposed Rule)

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. The CLFS final rule titled, Medicare Clinical Diagnostic Laboratory Tests Payment System final rule (CLFS final rule), published in the **Federal Register** on June 23, 2016, implemented section 1834A of the Act. Under the CLFS final rule (81 FR 41036), “reporting entities” must report to CMS during a “data reporting period” “applicable information” (that is, certain private payor data) collected during a “data collection period” for their component “applicable laboratories.” In general, the payment amount for each clinical diagnostic laboratory test (CDLT) on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the 6-month data collection period and reported to us during the 3-month data reporting period, and is equal to the weighted median of the private payor rates for the CDLT.

An applicable laboratory is defined at § 414.502, in part, as an entity that is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA) definition at § 493.2) that bills Medicare Part B under its own National Provider Identifier (NPI). In addition, an applicable laboratory is an entity that receives more than 50 percent of its

Medicare revenues during a data collection period from the CLFS and/or the Physician Fee Schedule. We refer to this component of the applicable laboratory definition as the “majority of Medicare revenues threshold.” The definition of applicable laboratory also includes a “low expenditure threshold” component, which requires an entity to receive at least \$12,500 of its Medicare revenues from the CLFS during a data collection period for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs).

In determining payment rates under the private payor rate-based CLFS, one of our objectives is to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts, for example, from independent laboratories, hospital outreach laboratories, and physician office laboratories, without imposing undue burden on those entities. We believe it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT, and minimizing the reporting burden for entities. In response to stakeholder feedback and in the interest of facilitating our goal, we are proposing to revise the majority of Medicare revenues threshold component of the definition of applicable laboratory at § 414.502(3) to exclude Medicare Advantage (MA) payments under Medicare Part C from the definition of total Medicare revenues (that is, the denominator of the majority of Medicare threshold equation). Specifically, the proposed change could allow additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C to meet the majority of Medicare revenues threshold and potentially qualify as applicable laboratories (if they also meet the low expenditure threshold) and report data to us.

As such, we believe this proposal may result in more data being reported, which we would use to set CLFS payment rates. However, with regard to the CLFS-related requirements and burden, we note that section 1834A(h)(2) of the Act provides that the Paperwork Reduction Act in chapter 35 of title 44 of the U.S.C. shall *not* apply to information collected under section 1834A of the Act (which is the new private payor rate-based CLFS).

For a complete discussion of our proposal to revise the majority of Medicare revenues threshold component of the definition of applicable laboratory under the

Medicare CLFS, we refer readers to section III.A of this proposed rule.

2. ICRs Regarding Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (§ 414.94 and Section III.D. of This Proposed Rule)

Consultations: In this rule we propose to revise the regulation at § 414.94(j) to allow the AUC consultation, when not performed personally by the ordering professional, to be performed by auxiliary personnel (as defined in § 410.26(a)(1)) under the direction of, and incident to, the ordering professional's services. The consultation requirements and burden will be submitted to OMB for approval under control number 0938–1345 (CMS–10654).

General practitioners make up a large group of practitioners who order applicable imaging services and would be required to consult AUC under this program so we use “family and general practitioner” from the list of BLS occupation titles (see Table O1) to calculate the following cost estimates. As our proposal would modify the AUC consultation requirement to allow auxiliary personnel, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation, we also use the “registered nurse” occupation to calculate our revised cost estimates.

To derive the burden associated with the proposed provision in § 414.94(j) that would take effect January 1, 2020, we estimate it would take 2 minutes (0.033 hr) at \$70.72/hr for auxiliary personnel in the form of a registered nurse to consult with a qualified CDSM. The Medicare Benefit Policy Manual (Pub. 100–02), Chapter 15, Section 60.2 IOM 100–02, Chapter 15, Section 60.2 requires that an incidental service performed by the nonphysician practitioner must have followed from a direct, personal, professional service furnished by the physician. Therefore, to estimate the percentage of consultations available to be performed incident to, we analyzed 2014 Medicare Part B claims comparing evaluation and management visits for new (CPT codes 99201, 99202, 99203, 99204, and 99205) relative to established (CPT codes 99211, 99212, 99213, 99214, 99215) patients with place of service codes 11 (physician's office). We found that approximately 10 percent of all claims incurred were for new patients. Therefore, we also estimate that 90-percent or 38,863,636 of the total consultations (43,181,818 total consultations × 0.90) could be performed by such auxiliary personnel, with the remaining 10 percent

(43,181,818 × 0.10) performed by the ordering professional. In aggregate, we estimate an annual burden of 1,282,500 hours (38,863,636.2 consultations × 0.033 hr/consultation) at a cost of \$90,698,400 (1,282,500 hr × \$70.72/hr) or \$2.33 per consultation. If this provision is finalized, we would continue to monitor our burden estimates and, if necessary, adjust those estimates for more precision once the program begins.

Additionally, the CY 2018 Physician Fee Schedule final rule (82 FR 52976) explicitly discussed and provided a voluntary period for ordering professionals to begin to familiarize themselves with qualified CDSMs. During the current 18-month voluntary participation period, we estimated there would be 10,230,000 consultations based on market research from current applicants for the qualification of their CDSMs for advanced diagnostic imaging services. Based on feedback from CDSMs with experience in AUC consultation, as well as standards recommended by the Office of the National Coordinator (ONC)³⁹ and the Healthcare Information Management Systems Society (HIMSS)⁴⁰, we estimated it would take 2 minutes (0.033 hr) at \$200.54/hr for a family and general practitioner or 2 minutes at \$70.72/hr for a registered nurse to use a qualified CDSM to consult specified applicable AUC. As mentioned above, we estimate that as many as 90-percent of practices would use auxiliary personnel working under the direction of the ordering professional to interact with the CDSM for AUC consultation. Consequently, we estimate a total burden of 337,590 hours (10,230,000 consultations × 0.033 hr) at a cost of \$28,256,958 [(337,590 hr × 0.10 × \$200.54/hr) + [337,590 hr × 0.90 × \$70.72/hr)]. Annually, we estimate 112,530 hours (337,590 hr/3 yr) at a cost of \$9,418,986 (\$28,256,958/3 yr). We are annualizing the one-time burden (by dividing our estimates by OMB's 3-year approval period) since we do not anticipate any additional burden after the 18-month voluntary participation period ends.

Beginning January 1, 2020, we anticipate 43,181,818 responses in the form of consultations based on the aforementioned market research, as well as Medicare claims data for advanced diagnostic imaging services. As noted above, we estimate it would take 2 minutes (0.033 hr) at \$200.54/hr for a

family and general practitioner or 2 minutes at \$70.72/hr for a registered nurse to use a qualified CDSM to consult specified applicable AUC. In aggregate, we estimate an annual burden of 1,425,000 hours (43,181,818 consultations × 0.033 hr/consultation) at a cost of \$119,275,350 [(0.1 × 1,425,000 hr × \$200.54/hr) + [0.9 × 1,425,000 hr × \$70.72/hr)].

Annual Reporting: Consistent with section 1834(q)(4)(B) of the Act, in the CY 2018 PFS final rule (82 FR 52976) we estimated the burden of implementing the one-time voluntary reporting period beginning in July 2018, and will be implementing the mandatory annual reporting requirement beginning January 1, 2020. Specifically, the regulation at § 414.94(k) requires that Medicare claims for advanced diagnostic imaging services, paid for under an applicable payment system (as defined in § 414.94(b)) and ordered on or after January 1, 2020, report the following information: (1) Identify which qualified CDSM was consulted by the ordering professional; (2) identify whether the service ordered would adhere to specified applicable AUC, would not adhere to specified applicable AUC, or whether specified applicable AUC was not applicable to the service ordered; and (3) identify the NPI of the ordering professional (if different from the furnishing professional). The reporting requirement will not have any impact on any Medicare claim forms because the forms' currently approved data fields, instructions, and burden are not expected to change. Consequently, there is no need for review by OMB under the authority of the PRA, however, we have assessed the impact and include an analysis to this effect in the regulatory impact section of this proposed rule.

Significant Hardship Exception: We propose to revise the regulation at § 414.94(i)(3) that provides for a significant hardship exception for ordering professionals who experience a significant hardship affecting their consultation of AUC when ordering an advanced diagnostic imaging service. The proposed revision would establish a process whereby all ordering professionals can self-attest that they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order. While this is not a certification being used as a substitute for a collection of AUC consultation information because no consultation is required by statute to take place, the significant hardship exception process would involve appending to the order for an applicable imaging service the significant hardship

information for inclusion on the Medicare claim in lieu of the AUC consultation information. This imposes no burden beyond the provision of identifying information and attesting to the applicable information. In this regard, the use of this process is not "information" as defined under 5 CFR 1320.3(h), and therefore, is exempt from requirements of the PRA.

Recordkeeping: Section 1834(q)(4)(C) of the Act provides for certain exceptions to these reporting requirements, therefore we believe that some claims for advanced diagnostic imaging services will not contain AUC consultation information, such as in the case of an ordering professional with a significant hardship. However, ordering professionals would store documentation supporting the self-attestation of a significant hardship. Storage of this information could involve the use of automated, electronic, or other forms of information technology at the discretion of the ordering professional. CMS estimates that the average time for office clerical activities associated with this storage of information to be 10 minutes (0.167 hr) at \$17.25/hr for a medical secretary to perform 6,699 recordkeeping actions, since consultation will not take place in the year when a hardship is incurred and 2016 data from the Medicare EHR Incentive Program and the first 2019 payment year MIPS eligibility and special status file suggests this estimate of those seeking hardship (control number 0938–1314). In aggregate we estimate an annual burden of 1,119 hours (6,699 recordkeeping activities × 0.167 hr) at a cost of \$19,303 (1,119 hr × \$17.25/hr). We seek comments to inform these burden estimates.

3. ICRs Regarding the Medicare Shared Savings Program (Part 425 and Section III.F. of This Proposed Rule)

Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the Shared Savings Program.

4. ICRs Regarding the Physician Self-Referral Law (42 CFR Part 411 and Section III.G. of This Proposed Rule)

Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing

³⁹ https://ecqi.healthit.gov/cds#quicktabs-tabs_cds3.

⁴⁰ <http://www.himss.org/improving-outcomes-cds-practical-pearls-new-himss-guidebook>.

another individual, entity, or third party payer) for those referred services. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. Additionally, the statute mandates refunding any amount collected under a bill for an item or service furnished under a prohibited referral. Finally, the statute imposes reporting requirements and provides for sanctions, including civil monetary penalty provisions.

As discussed in section III.G. of this rule, we are proposing regulatory updates to implement section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018), which added provisions to section 1877(h)(1) of the Act pertaining to the writing and signature requirements in certain compensation arrangement exceptions to the physician self-referral law's referral and billing prohibitions. Although we believe that the newly enacted provisions in section 1877(h)(1) of the Act are principally intended merely to codify in statute existing CMS policy and regulations with respect to compliance with the writing and signature requirements, we are proposing revisions to our regulations at 42 CFR 411.354(e) and 411.353(g) to address any actual or perceived difference between the statutory and regulatory language, to codify in regulation our longstanding policy regarding satisfaction of the writing requirement found in many of the exceptions to the physician self-referral law, and to make the Bipartisan Budget Act of 2018 policies applicable to compensation arrangement exceptions issued using the Secretary's authority in section 1877(b)(4) of the Act. The burden associated with the writing and signature requirements would be the time and effort necessary to prepare written documents and obtain signatures of the parties.

While the writing and signature requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the writing and signature requirements would be incurred by persons without federal regulation during the normal course of their activities. Specifically, we believe that, for normal business operations purposes, health care providers and suppliers document their financial arrangements with physicians and others in order to identify and be able to enforce the legal obligations of the parties. Therefore, we believe that the writing and signature requirements

should be considered usual and customary business practices.

5. The Quality Payment Program (QPP) (Part 414 and Section III.H. of This Proposed Rule)

Summary: With respect to the PRA, the Quality Payment Program is comprised of a series of ICRs associated with MIPS and Advanced APMs. The MIPS ICRs consist of registration for virtual groups; qualified registry and QCDR self-nomination; CAHPS survey vendor application; Quality Payment Program Identity Management Application Process; quality performance category data submission by claims collection type, QCDR and MIPS CQM collection type, eCQM collection type, and CMS web interface submission type; CAHPS for MIPS survey beneficiary participation; group registration for CMS web interface; group registration for CAHPS for MIPS survey; call for quality measures; Promoting Interoperability reweighting applications; Promoting Interoperability performance category data submission; call for Promoting Interoperability measures; improvement activities performance category data submission; nomination of improvement activities; and opt-out of Physician Compare for voluntary participants. ICRs for Advanced APMs consist of partial qualifying APM participant (QP) election; other payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of data for All-Payer QP determinations under the All-Payer combination option.

The following ICRs reflect this proposed rule's policies, as well as policies in the CY 2017 (81 FR 77008) and CY 2018 (82 FR 53568) Quality Payment Program final. In discussing each ICR, we reference the specific policies and whether they are proposed in this CY 2019 proposed rule or finalized in the CY 2017 or CY 2018 Quality Payment Program final rules. As described below in more detail, two ICRs (Quality: CMS Web Interface Submission Type, and Promoting Interoperability Performance Category: Data Submission) show a reduction in burden due to proposed changes in policies. Most burden estimates are adjustments to reflect data available at the time of publication of this proposed rule. Finally, we added one ICR to incorporate a collection previously mentioned in the CY 2018 Quality Payment Program final rule for which collection had not yet started: Submission of Data for All-Payer QP Determinations (82 FR 53886). See section V.B.4. of this proposed rule for

a summary of the ICRs, the overall burden estimates, changes in burden due to policies in this proposed rule, and a summary of the policy and data changes affecting each ICR.

The revised requirements and burden estimates for all Quality Payment Program ICRs (except for CAHPS for MIPS and virtual groups election) will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). The proposed CAHPS for MIPS ICRs will be submitted to OMB for approval under control number 0938–1222 (CMS–10450). The Virtual Groups Election is approved by OMB control number 0938–1343 (CMS–10652).

With regard to Quality Payment Program respondents, we selected BLS occupations Billing and Postal Clerks, Computer Systems Analysts, Physicians, Practice Administrator, and Licensed Practical Nurse (see Wage Estimates in section V.A. of this proposed rule) based on a study (Casalino et al., 2016) that collected data on the staff in physician's practices involved in the quality data submission process.⁴¹ To calculate the cost for virtual groups to prepare their written formal agreements, we used wage estimates for Legal Support Workers, All Others.

Respondent estimates are modeled using similar methodology to the CY 2017 and CY 2018 Quality Payment Program final rules. For instance, we are using the eligibility file generated for the MIPS program based on the first 12-month determination period for the first year; the APM Participation List for the third snapshot date of the 2017 QP performance period to identify QP clinicians excluded from MIPS, and to identify clinicians and groups eligible for MIPS but who are not required to submit data for the Promoting Interoperability performance category; and the 2016 PQRS data and 2016 Medicare and Medicaid EHR Incentive Program data to estimate the number of respondents for the improvement activities performance category. Although the submission period for the 2017 MIPS performance period ended in April 2018, the participation and performance data were not available at the time of writing this proposed rule, with the sole exception of 286 CMS Web Interface respondents, which is based on the number of groups who submitted MIPS data via the CMS Web Interface during the 2018 MIPS performance period. We intend to update our burden

⁴¹ Lawrence P. Casalino et al., "US Physician Practices Spend More than \$15.4 Billion Annually to Report Quality Measures," *Health Affairs*, 35, no. 3 (2016): 401–406.

estimates in the final rule using actual MIPS data if technically feasible.

Our estimates assume clinicians who participated in 2016 PQRS and who are not determined to be QPs based on their participation in Advanced APMs in the 2017 performance period will continue to submit quality data in the 2019 MIPS performance period. This assumption is consistent with the CY 2017 and CY 2018 Quality Payment Program final rules where we assumed that clinicians would continue to participate as either MIPS eligible clinicians or voluntary reporters (81 FR 77501 and 82 FR 53908). As discussed in section III.H.3.a. of this proposed rule, we are proposing to revise the eligibility criteria to expand MIPS to additional clinician types. In addition, we are proposing in section III.H.3.c. of this proposed rule to revise the low-volume threshold in the following manner: If a MIPS eligible clinician meets or exceeds one, but not all, of the low-volume threshold criterion, including as defined by dollar amount (\$90,000), beneficiary count (200), or covered professional services to Part-B enrolled individuals (minimum threshold of 200) then they may elect to submit data and opt-in to MIPS. If a MIPS eligible clinician does not meet at least one of these low-volume determinations or does not elect to opt-in, they are not eligible and are excluded from MIPS. If they are excluded and submit data, they would be voluntary reporters. If these policies are finalized, it would expand the number of potential MIPS eligible clinicians, but we do not anticipate an incremental increase in the burden because the affected clinicians were assumed to be voluntary reporters in prior rules. In the CY 2018 Quality Payment Program final rule, clinicians who participated in 2016 PQRS, and who were not determined to be QPs based on their participation in Advanced APMs during CY 2017 and were not MIPS eligible, were assumed to be voluntary reporters in MIPS (82 FR 53908). Therefore, the proposed expansion in MIPS eligibility does not change the total number of respondents, but instead shifts a certain number of assumed voluntary reporters to MIPS eligible clinicians.

Additionally, we expect the act of electing to be a single click once a clinician or group has submitted data;

therefore, we do not anticipate that proposal would revise the burden hours for any of our burden estimates.

Our participation estimates are reflected in Tables 65, 66, and 67 for the quality performance category, Table 78 for the Promoting Interoperability performance category, and Table 81 for the improvement activities performance category. We also assume that previous PQRS participants who are not QPs will submit data for the improvement activities performance category, and will submit data for the Promoting Interoperability performance category unless they receive a significant hardship or other type of exception or are automatically assigned a weighting of zero percent for the Promoting Interoperability performance category.

Due to data limitations, our burden estimates may overstate the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories. This is due to two primary reasons. First, we anticipate the number of QPs to increase because of total expected growth in Advanced APM participation. The additional QPs would be excluded from MIPS and likely not report. Second, we anticipate that some portion of the clinicians that opted to participate in PQRS may elect to not participate in MIPS, and, therefore, the actual number of participants may be lower than our estimates. However, we believe our estimates are the most appropriate given the available data.

Framework for Understanding the Burden of MIPS Data Submission: Because of the wide range of information collection requirements under MIPS, Table 62 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians varies across the types of data, and whether the clinician is a MIPS eligible clinician, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 62, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same requirements as groups, therefore

we will refer only to groups for the remainder of this section unless otherwise noted. Because MIPS eligible clinicians are not required to provide any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 62.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. For the 2019 MIPS performance period, the quality data submitted by Shared Savings Program ACOs, Next Generation ACOs, and other APM Entities on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit Promoting Interoperability performance category data individually. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we describe that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Advanced APM participants who are determined to be Partial QPs may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844), but other than the election to participate in MIPS, we do not have data to estimate that burden.

TABLE 62—CLINICIANS OR ORGANIZATIONS SUBMITTING MIPS DATA ON BEHALF OF CLINICIANS, BY TYPE OF DATA AND CATEGORY OF CLINICIAN *

Category of clinician	Type of data submitted			
	Quality performance category	Promoting interoperability performance category	Improvement activities performance category	Other data submitted on behalf of MIPS eligible clinicians
MIPS Eligible Clinicians (not in MIPS APMs) and Other Eligible Clinicians Voluntarily Submitting Data ^a .	As group or individual clinicians.	As group or individual clinicians. Clinicians who are hospital-based, ambulatory surgical center-based, non-patient facing, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists, occupational therapists, clinical social workers, and clinical psychologists are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians approved for significant hardship or other exceptions are also eligible for a zero percent weighting.	As group or individual clinicians.	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. Virtual groups must register via email.
Eligible Clinicians participating in the Shared Savings Program or Next Generation ACO Model (both MIPS APMs).	ACOs submit to the CMS Web Interface and CAHPS for ACOs on behalf of their participating MIPS eligible clinicians. [These submissions are not included in burden estimates for this proposed rule because quality data submission to fulfill requirements of the Shared Savings Program and for purposes of testing and evaluating the Next Generation ACO Model are not subject to the PRA.] ^b	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [Burden estimates for this proposed rule assume group TIN-level reporting.] ^c	CMS will assign the improvement activities performance category score to each APM Entity group based on the activities involved in participation in the Shared Savings Program. ^d [The burden estimates for this proposed rule assume no improvement activity reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity performance category score.]	Advanced APM Entities will make election for participating MIPS eligible clinicians.
Eligible Clinicians participating in Other MIPS APMs.	APM Entities submit to MIPS on behalf of their participating MIPS eligible clinicians. [These submissions are not included in burden estimates for this proposed rule because quality data submission for purposes of testing and evaluating Innovation Center models tested under Section 1115A of the Social Security Act (or Section 3021 of the Affordable Care Act) are not subject to the PRA.]	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [The burden estimates for this proposed rule assume group TIN-level reporting.]	CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM. [The burden estimates for this proposed rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score.]	Advanced APM Entities will make election for participating eligible clinicians.

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

^a Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

^b Sections 1899 and 1115A of the Act state the Shared Savings Program and testing, evaluation, and expansion of Innovation Center models are not subject to the PRA (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively).

^c Both group TIN and individual clinician Promoting Interoperability data will be accepted. If both group TIN and individual scores are submitted for the same APM Entity, CMS would take the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for the APM Entity score.

^d APM Entities participating in MIPS APMs do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules and proposed in this CY 2019 rule create some additional data collection requirements not listed in Table 62. These additional data collections, some of which were previously approved by OMB under the control numbers 0938–1314 (Quality Payment Program) and 0938–1222 (CAHPS for MIPS), are as follows:

Additional approved ICRs related to MIPS third-party vendors

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508 and 82 FR 53906 through 53908) (0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508 and 82 FR 53906 through 53908) (0938–1314).

- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (0938–1222).

Additional ICRs related to the data submission and the quality performance category

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509 and 82 FR 53916 through 53917) (0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914).

Additional ICRs related to the Promoting Interoperability performance category

- Application for Promoting Interoperability Reweighting (82 FR 53918) (0938–1314).

Additional ICRs related to call for new MIPS measures and activities

- Nomination of improvement activities (82 FR 53922) (0938–1314).
- Call for new Promoting Interoperability measures (0938–1314).
- Call for new quality measures (0938–1314).

Additional ICRs related to MIPS

- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS (82 FR 53924 through 53925) (0938–1314).

Additional ICRs related to APMs

- Partial QP Election (81 FR 77512 through 77513 and 82 FR 53922 through 53923) (0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924) (0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician

Initiated Process (82 FR 53924) (0938–1314).

- Submission of Data for All-Payer QP Determinations (New data collection for the 2019 performance period).

6. Quality Payment Program ICRs Regarding the Virtual Group Election (§ 414.1315)

This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not making any virtual group election changes under that control number.

7. Quality Payment Program ICRs Regarding Third-Party Reporting (§ 414.1400)

Under MIPS, quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as one quality performance category measure, can be submitted via CMS-approved survey vendors. In the CY 2018 Quality Payment Program final rule, we combined the burden for self-nomination of qualified registries and QCDRs (82 FR 53906). For this proposed rule, we determined that requirements for self-nomination for qualified registries were sufficiently different from QCDRs that it is necessary to estimate the two independently. The change would align the burden more closely to the requirements for QCDRs and qualified registries to self-nominate, not because of any change in policy in this proposed rule. Specifically, while the processes for self-nomination are similar, QCDRs have the option to submit QCDR measures for the quality performance category. Therefore, differences between QCDRs and registries self-nomination are associated with the preparation of QCDR measures for approval. The burden associated with qualified registry self-nomination, QCDR self-nomination, and the CAHPS for MIPS survey vendor applications follow:

Qualified Registry Self-Nomination:
The proposed requirements and burden

associated with qualified registry self-nomination will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Qualified registries interested in submitting MIPS data to us on their participants' behalf need to complete a self-nomination process to be considered qualified to submit on behalf of MIPS eligible clinicians or groups (82 FR 53815).

In the CY 2018 Quality Payment Program final rule, previously approved qualified registries in good standing (that are not on probation or disqualified) that wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable (82 FR 53815). In the same rule, qualified registries in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved qualified registry application, for CMS review during the self-nomination period, from September 1 to November 1 (82 FR 53815). This simplified self-nomination process will begin for the 2019 MIPS performance period.

The CY 2017 Quality Payment Program final rule provided the definition of a qualified registry to be a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification criteria specified by CMS for that performance period (81 FR 77382).

For this CY 2019 Quality Payment Program rule, we are proposing adjustments to the number of respondents (from 120 to 150) based on more recent data and a revised definition of “respondent” to account for self-nomination applications received but not approved. We are also proposing adjustments to our per respondent time estimate (from 10 hours to 3 hours) based on our review of the current burden estimates against the existing policy. Additionally, we are proposing a range of time estimates

(from 10 hours to 0.5 hours) which reflect the availability of a simplified self-nomination process for previously approved qualified registries.

For the 2017 MIPS performance period, we received 138 applications for nomination to be a qualified registry and 145 applications for the 2018 MIPS performance period. In continuance of this trend for the 2019 MIPS performance period, we estimate 150 nomination applications will be received from qualified registries desiring approval to report MIPS data, an increase of 30 respondents.

For this proposed rule, the burden associated with qualified registry self-nomination will vary depending on the number of existing qualified registries that will elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53815). The self-nomination form is submitted electronically using the web-based tool JIRA. For the CY 2018 performance period, 141 qualified registries were approved to submit MIPS data.

In the CY 2018 Quality Payment Program final rule, we estimated the burden associated with self-nomination of a qualified registry to be 10 hours, similar to PQRS (82 FR 53907). For this proposed rule, we reduce our estimate to 3 hours because registries no longer provide an XML submission, calculated measure, or measure flow as part of the self-nomination process and are not subject to a mandatory interview, which were done previously as part of the PQRS qualified registry self-nomination process, upon which the previous assumption of 10 hours was based. As described in the CY 2017 Quality Payment Program final rule, the full self-nomination process requires the submission of basic information, a

description of the process the qualified registry will use for completion of a randomized audit of a subset of data prior to submission, and the provision of a data validation plan along with the results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384).

For the simplified self-nomination process, we estimate 0.5 hours per qualified registry to submit a nomination, a reduction of 9.5 hours from currently approved estimates.

As shown in Table 63, we estimate that the staff involved in the qualified registry self-nomination process will be mainly computer systems analysts or their equivalent, who have an adjusted labor cost of \$89.18/hour. Assuming that the time associated with the self-nomination process ranges from a minimum of 0.5 hours (for the simplified self-nomination process) to 3 hours (for the full self-nomination process) per qualified registry, we estimate that the annual burden will range from 97.5 hours $[(141 \text{ qualified registries} \times 0.5 \text{ hr}) + (9 \text{ qualified registries} \times 3 \text{ hr})]$ to 450 hours $(150 \text{ qualified registries} \times 3 \text{ hr})$ at a cost ranging from \$8,695 $(97.5 \text{ hr} \times \$89.18/\text{hr})$ to \$40,131 $(450 \text{ hr} \times \$89.18/\text{hr})$, respectively (see Table 63).

Independent of the change to our per response time estimate, the increase in the number of respondents results in an adjustment of 300 hours and \$26,754 $(30 \text{ registries} \times 10 \text{ hr} \times \$89.18/\text{hr})$. Accounting for the change in the number of qualified registries, the change in time per qualified registry to self-nominate results in an adjustment of between $-1,402.5$ hours and $-125,075$ $[(141 \text{ registries} \times -9.5 \text{ hr}) + [(9 \text{ registries} \times -7 \text{ hr})] \text{ at } \$89.18/\text{hr}]$ and $-1,050$ hours and $-\$93,639$ $(150 \text{ registries} \times -7 \text{ hr} \times \$89.18/\text{hr})$. When

these two adjustments are combined, the net impact ranges between $-1,102.5$ $(-1,402.5 + 300)$ and -750 $(-1,050 + 300)$ hours and $-\$98,321$ $(-\$125,075 + \$26,754)$ and $-\$66,885$ $(-\$93,639 + \$26,754)$.

Qualified registries must comply with requirements on the submission of MIPS data to CMS. The burden associated with the qualified registry submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the qualified registry by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. These requirements are currently approved by OMB under control number 0938–1314 (CMS–10621) with no changes being proposed.

We expect that the time needed for a qualified registry to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the qualified registry and the number of applicable measures. However, we believe that qualified registries already perform many of these activities for their participants. We believe the estimates discussed above and shown in Table 63 represents the upper bound of registry burden, with the potential for less additional MIPS burden if the registry already provides similar data submission services.

Based on the assumptions previously discussed, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered “qualified” to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 63—ESTIMATED BURDEN FOR QUALIFIED REGISTRY SELF-NOMINATION

	Minimum burden	Maximum burden
Number of Qualified Registry Simplified Self-Nomination Applications submitted (a)	141	0
Number of Qualified Registry Full Self-Nomination Applications submitted (b)	9	150
Total Annual Hours Per Qualified Registry for Simplified Process (c)	0.5	0.5
Total Annual Hours Per Qualified Registry for Full Process (d)	3	3
Total Annual Hours for Qualified Registries (e) = (a) * (c) + (b) * (d)	97.5	450
Cost Per Simplified Process Per Registry (@computer systems analyst's labor rate of \$89.18/hr.) (f)	\$44.59	\$44.59
Cost Per Full Process Per Registry (@computer systems analyst's labor rate of \$89.18/hr.) (g)	\$267.54	\$267.54
Total Annual Cost for Qualified Registries (h) = (a) * (f) + (b) * (g)	\$8,695	\$40,131

Both the minimum and maximum burden shown in Table 64 will be submitted for approval to OMB under

control number 0938–1314 (CMS–10621) and reflect adjustments due to review of self-nomination process and

the number of respondents. For purposes of calculating total burden associated with the proposed rule as

shown in Table 89, only the maximum burden will be used.

*QCDR Self-Nomination:*⁴² The proposed requirements and burden associated with QCDR self-nomination will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

QCDRs interested in submitting quality, Promoting Interoperability, and improvement activities performance category data to us on their participants' behalf will need to complete a self-nomination process to be considered qualified to submit on behalf of MIPS eligible clinicians or groups.

In the CY 2018 Quality Payment Program final rule, previously approved QCDRs in good standing (that are not on probation or disqualified) that wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable (82 FR 53808). Existing QCDRs in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved QCDR application, for CMS review during the self-nomination period, from September 1 to November 1 (82 FR 53808). This simplified self-nomination process will begin for the 2019 MIPS performance period.

For this proposed rule, the burden associated with QCDR self-nomination will vary depending on the number of existing QCDRs that will elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53808 through 53813). The self-nomination form is submitted electronically using the web-based tool JIRA. For the CY 2018 performance period, 150 QCDRs were approved to submit MIPS data.

For this CY 2019 Quality Payment Program rule, we are proposing adjustments to the number of respondents (from 113 to 200) based on more recent data and a revised definition of "respondent" to account for self-nomination applications received but not approved. We are also proposing adjustments to the time burden estimates per respondent based on our review of the current burden estimates against the existing policy as well as proposing a range of time

burden estimates which reflect the availability of a simplified self-nomination process for previously approved QCDRs.

For the 2017 MIPS performance period, we received 138 self-nomination applications from QCDRs and for the 2018 MIPS performance period, we received 176 self-nomination applications. In continuance of this trend for the 2019 MIPS performance period, we estimate 200 self-nomination applications will be received from QCDRs desiring approval to report MIPS data, an increase of 87 respondents.

We estimate that the self-nomination process for QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 3 hours per QCDR to submit information required at the time of self-nomination as described in the CY 2017 Quality Payment Program final rule including basic information about the QCDR, describe the process it will use for completion of a randomized audit of a subset of data prior to submission, provide a data validation plan, and provide results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). However, for the simplified self-nomination process, we estimate 0.5 hours per QCDR to submit this information. The self-nomination form is submitted electronically using the web-based tool JIRA.

In addition, QCDRs calculate their measure results. QCDRs must possess benchmarking capabilities (for QCDR measures) that compare the quality of care a MIPS eligible clinician provides with other MIPS eligible clinicians performing the same quality measures. For QCDR measures, the QCDR must provide to us, if available, data from years prior (for example, 2017 data for the 2019 MIPS performance period) before the start of the performance period. In addition, the QCDR must provide to us, if available, the entire distribution of the measure's performance broken down by deciles. As an alternative to supplying this information to us, the QCDR may post this information on their website prior to the start of the performance period, to the extent permitted by applicable privacy laws. The time it takes to perform these functions may vary depending on the sophistication of the entity, but we estimate that a QCDR will spend an additional 1 hour performing these activities per measure and assume that each QCDR will submit information for 9 QCDR measures, for a total burden of 9 hours per QCDR (1 hr per measure × 9 measures). The estimated average of

9 measures per QCDR is based on the number of QCDR measure submissions received in the 2017 and 2018 MIPS performance periods and is the same for each QCDR regardless of whether they elect to use the simplified or full self-nomination process.

In the 2017 MIPS performance period, we received over 1,000 QCDR measure submissions. In the 2018 MIPS performance period, we received over 1,400 QCDR measure submissions. For the 2019 MIPS performance period, we anticipate this trend will continue, and therefore, estimate we will receive a total of approximately 1,800 QCDR measure submissions, resulting in an average of 9 measure submissions per QCDR (1,800 measure submissions/200 QCDRs).

In the CY 2018 Quality Payment Program final rule, the burden associated with self-nomination of a QCDR was estimated to be 10 hours (82 FR 53907). For this proposed rule, we are increasing the burden associated with self-nomination to 12 hours because QCDRs are no longer required provide an XML submission and are not subject to a mandatory interview; both of which were completed as part of the PQRS QCDR self-nomination process upon which the previous assumption of 10 hours was based, while simultaneously accounting for an increase in the number of QCDR measure submissions being submitted.

As shown in Table 64, we estimate that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor cost of \$89.18/hr. Assuming that the hours per QCDR associated with the self-nomination process ranges from a minimum of 9.5 hours (for the simplified self-nomination process) to 12 hours (for the full self-nomination process), we estimate that the annual burden will range from 2,025 hours $([150 \text{ QCDRs} \times 9.5 \text{ hr}] + [50 \text{ QCDRs} \times 12 \text{ hr}])$ to 2,400 hours $(200 \text{ QCDRs} \times 12 \text{ hr})$ at a cost ranging between \$180,590 $(2,025 \text{ hr} \times \$89.18/\text{hr})$ and \$214,032 $(2,400 \text{ hr} \times \$89.18/\text{hr})$, respectively (see Table 64).

Independent of the change to our per response time estimate, the increase in the number of respondents results in an adjustment of 870 hours and \$77,587 $(87 \text{ registries} \times 10 \text{ hr} \times \$89.18/\text{hr})$. Accounting for the change in the number of qualified registries, the change in time per QCDR to self-nominate results in an adjustment of between 25 hours and \$2,230 $([150 \text{ registries} \times -0.5 \text{ hr}] + [50 \text{ registries} \times 2 \text{ hr}] \text{ at } \$89.18/\text{hr})$ and 400 hours and \$35,672 $(200 \text{ registries} \times 2 \text{ hr} \times \$89.18/\text{hr})$.

⁴² We do not anticipate any changes in the CEHRT process for health IT vendors as we transition to MIPS. Hence, health IT vendors are not included in the burden estimates for MIPS.

hr). When these two adjustments are combined, the net impact ranges between 895 (870 + 25) hours at \$79,817 (\$77,587 + \$2,230) and 1,270 (870 + 400) hours at \$113,259 (\$77,587 + \$35,672).

QCDRs must comply with requirements on the submission of MIPS data to CMS. The burden associated with the QCDR submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the QCDR by its participants and submitting these results, the numerator

and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. These requirements are currently approved by OMB under control number 0938–1314 (CMS–10621) with no changes being proposed. We expect that the time needed for a QCDR to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the QCDR and the number of applicable measures. However, we believe that QCDRs already perform

many of these activities for their participants. We believe the estimate noted in this section represents the upper bound of QCDR burden, with the potential for less additional MIPS burden if the QCDR already provides similar data submission services.

Based on the assumptions previously discussed, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered “qualified” to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 64—ESTIMATED BURDEN FOR QCDR SELF-NOMINATION

	Minimum burden	Maximum burden
Number of QCDR Simplified Self-Nomination Applications submitted (a)	150	0
Number of QCDR Full Self-Nomination Applications submitted (b)	50	200
Total Annual Hours Per QCDR for Simplified Process (c)	9.5	9.5
Total Annual Hours Per QCDR for Full Process (d)	12	12
Total Annual Hours for QCDRs (e) = (a) * (c) + (b) * (d)	2,025	2,400
Cost Per Simplified Process Per QCDR (@computer systems analyst's labor rate of \$89.18/hr.) (f)	\$847.21	\$847.21
Cost Per Full Process Per QCDR (@computer systems analyst's labor rate of \$89.18/hr.) (g)	\$1,070.16	\$1,070.16
Total Annual Cost for QCDRs (h) = (a) * (f) + (b) * (g)	\$180,590	\$214,032

Both the minimum and maximum burden shown in Table 64 will be submitted for approval to OMB under control number 0938–1314 (CMS–10621) and reflect adjustments due to review of self-nomination process and the number of respondents. For purposes of calculating total burden associated with the proposed rule as shown in Table 89, only the maximum burden will be used.

CMS-Approved CAHPS for MIPS Survey Vendors: This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to CMS-approved CAHPS for MIPS survey vendors. The CMS-approved CAHPS for MIPS survey vendor requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any MIPS survey vendor changes under that control number.

8. Quality Payment Program ICRs Regarding Data Submission (§§ 414.1325 and 414.1335)

Under our current policies, two groups of clinicians will submit quality data under MIPS: Those who submit as MIPS eligible clinicians and other eligible clinicians who opt to submit data voluntarily but will not be subject to MIPS payment adjustments. While the proposed expansion of the

definition of a MIPS eligible clinician to new clinician types and the opt-in process for MIPS participation discussed in sections III.H.3.a and III.H.3.c.(6) of this proposed rule could affect respondent counts, all of the new potential respondents had the opportunity to participate in PQRS. Therefore, consistent with our assumptions in the CY 2017 and CY 2018 Quality Payment Program final rules that PQRS participants that are not QPs would have participated in MIPS as voluntary respondents (81 FR 77501 and 82 FR 53908, respectively), we anticipate that this rule's proposed expansion of the definition of a MIPS eligible clinician will not have any incremental effect on any of our currently approved burden estimates. Our respondent assumptions regarding QPs have been updated using the APM Participation List for the third snapshot date of the 2017 QP performance period in place of the 2017 QP determination data used to estimate respondents in the CY 2018 Quality Payment Program final rule (82 FR 53908). With this exception, our respondent assumptions remain the same as approved in the approved PRA.

For the purpose of the following analyses, we assume that a total of 763,383 clinicians who participated in PQRS for the reporting periods occurring in 2016 and who are not QPs in Advanced APMs in the 2017 MIPS

performance period will continue to submit quality data in the 2019 MIPS performance period. This number differs from the currently approved estimate (OMB 0938–1314, CMS–10621) of 134,802 due to more QPs being identified and removed. We assume that 100 percent of APM Entities in MIPS APMs will submit quality data to CMS as required under their models.⁴³

As discussed in section III.H.3.h.(1).(b) of this proposed rule, we are proposing to replace the term “submission mechanism” with the terms “collection type” and “submission type.” “Submission mechanism” is presently used to refer not only to the mechanism by which data is submitted, but also to certain types of measures and activities on which data are submitted to the entities submitting such data in the Quality Payment Program.

Apart from clinicians that became QPs in the 2017 MIPS performance period, we assume that clinicians will continue to submit quality data for the same collection types they used under the 2016 PQRS. As discussed in the CY

⁴³ We estimate that 120,508 clinicians that participated in the 2016 PQRS will be QPs who will not be not required to submit MIPS quality performance category data under MIPS, and are not included in the numerator or denominator of our participation rate. This is a difference of 19,859 compared to the number of QPs in the CY 2018 Quality Payment Program final rule (82 FR 53908).

2018 Quality Payment Program final rule (82 FR 53905), when describing the burden for the virtual group application process, we assume that the 80 TINs that elect to form 16 virtual groups will continue to collect and submit MIPS data using the same collection and submission types as they did when reporting under the 2016 PQRS, but the submission will be at the virtual group, rather than group level. Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their models. The burden is excluded as sections 3021 and 3022 of the Affordable Care Act state the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA (42 U.S.C. 1395jj(e) and 1315a(d)(3), respectively).⁴⁴ Tables 65, 66, and 67 explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians segregated by collection type.

Table 65 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2019 MIPS performance period. First, we estimated the number of clinicians that submit data as an individual clinician or group during the 2019 MIPS performance period using 2016 PQRS data on individuals and groups by collection type and excluded clinicians identified as QPs using the APM Participation List for the third snapshot date of the 2017 QP performance period.

For the 2019 performance period, respondents will have the option to submit quality performance category data via claims, direct, log in and upload, and CMS Web Interface submission types. For this proposed rule, participation data by submission type and user research data to inform burden assumptions are not available to estimate burden by submission type. As a result, we continue to estimate the burden for collecting data via collection type: Claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. As

we gain more experience with the program, we may revise this approach in the future.

For the claims collection type, in section III.H.3.h.(1)(b) of this rule, we propose to limit the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and to allow clinicians in small practices to report claims as a group. We assume in our currently approved burden analysis that any clinician that submits quality data codes to us for the claims collection type is intending to do so for the Quality Payment Program. We made this assumption originally in the CY 2016 Quality Payment Program final rule to ensure that we fully accounted for any burden that may have resulted from our policies. In some cases, however, clinicians may be submitting quality data codes not only for claims collection type, but also for MIPS CQM and QCDR collection types. Some registries and QCDRs utilize data from claims to populate their datasets when submitting on behalf of clinicians. We are not able to separate out when a clinician submits a quality data code solely for the claim collection type or when a clinician is also submitting these codes for MIPS CQM or QCDR collection types. In addition, we see a large number of voluntary reporters for the claims collection type.

Approximately half of the 274,702 clinicians we estimate will submit quality data via claims (see Table 65) are MIPS eligible clinicians while the other half are voluntary reporters which means our burden include estimates for a large number of voluntary reporters. Approximately 60 percent of these 274,702 clinicians are in practices with more than 15 clinicians; however, over 80 percent of the number in practices larger than 15 clinicians are either voluntary reporters, group reporters, or are also reporting quality data through another collection type. Approximately 25,000 clinicians in non-small practices are both MIPS eligible and scored based only on claims data. Overall, we find that approximately 47 percent of the clinicians reporting claims in non-small practices would also qualify for facility-based reporting, and therefore, would not be required to submit quality data. It is unclear why many clinicians are submitting quality data via an alternate collection type and we currently lack data to estimate both the number of clinicians who would be impacted by this proposal and the potential behavioral response of those clinicians

who would be required to switch to another collection type. As a result, we propose to continue using the assumption that all clinicians (except QPs) who submitted data to 2016 PQRS via the claims collection type would continue to do so for MIPS in order to avoid overstating the impact of the proposed change. We intend to update this burden estimate with additional data as it becomes available. We also seek comment on potential other assumptions for capturing the claims burden.

Due to data limitations, our burden estimates for all quality collection types continue to assume that clinicians who submitted data in PQRS (except QPs) would continue to do so using the same collection types in MIPS. Using our proposed terminology, clinicians who used a QCDR or Registry would now collect measures via QCDR or MIPS CQM collection type; clinicians who used the EHR in PQRS would elect the eCQM collection type, and groups that elected the CMS Web Interface for PQRS would elect the CMS Web Interface for MIPS.

In addition, participation data for the 2017 MIPS performance period was unavailable in time for this proposed rule, with the exception of CMS Web Interface respondents. If actual participation data for the 2017 MIPS performance period is available in time to meet our final rule's publication schedule, we will use this data and revise our estimates in that rule. Based on these methods, Table 65 shows that in the 2019 MIPS performance period, an estimated 274,702 clinicians will submit data as individuals for the claims collection type; 267,736 clinicians will submit data as individuals or as part of groups for the MIPS CQM or QCDR collection types; 129,188 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 91,757 clinicians will submit as part of groups via the CMS Web Interface.

Table 65 provides estimates of the number of clinicians to collect quality measures data via each collection type, regardless of whether they decide to submit as individual clinicians or as part of groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups.

⁴⁴ Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their models.

TABLE 65—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE

	Claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of clinicians to collect data by collection type (as individual clinicians or groups) in Quality Payment Program Year 3 (excludes QPs) (a)	274,702	267,736	129,188	91,757	763,383
* Number of clinicians to collect data by collection type (as individual clinicians or groups) in Quality Payment Program Year 2 (excludes QPs) (b)	278,039	255,228	131,133	93,867	758,267
Difference between Year 3 and Year 2 (c) = (a) – (b)	–3,337	+12,508	–1,945	–2,110	+5,116

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

In the CY 2018 Quality Payment Program final rule (82 FR 53625 through 53626), beginning with the 2019 MIPS performance period, we allow MIPS eligible clinicians to submit data for multiple collection types for a single performance category. Therefore, we are capturing the burden of any eligible clinician that may have historically collected to PQRS via multiple collection types, as we assume they would continue to collect via multiple collection types and that our MIPS

scoring methodology will take the highest score. Hence, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive, and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types under the 2016 PQRS.

Table 66 uses methods similar to those described for Table 65 to estimate the number of clinicians to submit data as individual clinicians via each

collection type in Quality Payment Program Year 3. We estimate that approximately 274,702 clinicians will submit data as individuals using the claims collection type; approximately 103,268 clinicians will submit data as individuals using MIPS CQMs or QCDR collection types; and approximately 52,028 clinicians will submit data as individuals using eCQMs collection type.

TABLE 66—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA AS INDIVIDUALS BY COLLECTION TYPE

	Claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of Clinicians to submit data as individuals in Quality Payment Program Year 3 (excludes QPs) (a)	274,702	103,268	52,028	0	429,998
* Number of Clinicians to submit data as individuals in Quality Payment Program Year 2 (excludes QPs) (b)	278,039	104,281	52,709	0	435,029
Difference between Year 3 and Year 2 (c) = (a) – (b)	–3,337	–1,013	–681	0	–5,031

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

To be consistent with the policy in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points, our columns in Table 66 are not mutually exclusive.

Table 67 provides our estimated counts of groups or virtual groups to submit quality data on behalf of clinicians for each collection type in the 2019 MIPS performance period and reflects our assumption that the formation of virtual groups will reduce burden. Except for groups comprised entirely of QPs, we assume that groups that submitted quality data as groups under the 2016 PQRS will continue to submit quality data either as groups or virtual groups for the same collection types as they did as a group or TIN

within a virtual group for the 2019 MIPS performance period. The first step was to estimate the number of groups or virtual groups to collect data via each collection type during the 2019 MIPS performance period using 2016 PQRS data on groups collecting through various collection types and excluding clinicians identified as QPs using the APM Participation List for the third snapshot date of the 2017 QP performance period. The second and third steps in Table 67 reflect our currently approved assumption that virtual groups will reduce the burden for quality data submission by reducing the number of organizations to submit quality data on behalf of clinicians. We assume that 40 groups that previously collected on behalf of clinicians via QCDR or MIPS CQM collection types will elect to form 8 virtual groups that will collect via QCDR and MIPS CQM collection types. We assume that another 40 groups that previously collected on behalf of clinicians via

eCQM collection types will elect to form another 8 virtual groups that will collect via eCQM collection types. Hence, the second step in Table 67 is to subtract out the estimated number of groups under each collection type that will elect to form virtual groups, and the third step in Table 67 is to add in the estimated number of virtual groups that will submit on behalf of clinicians for each collection type.

Specifically, we assumed that 3,788 groups and virtual groups will submit data for the QCDR or MIPS CQM collection types on behalf of 164,468 clinicians; 1,501 groups and virtual groups will submit for eCQM collection types on behalf of 77,160 eligible clinicians; and 286 groups will submit data via the CMS Web Interface on behalf of 91,757 clinicians. Groups cannot elect to collect via claims collection type.

TABLE 67—ESTIMATED NUMBER OF GROUPS AND VIRTUAL GROUPS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE ON BEHALF OF CLINICIANS

	Claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of groups to collect data by collection type (on behalf of clinicians) in Quality Payment Program Year 3 (excludes QPs) (a)	0	3,820	1,533	286	5,639
Subtract out: Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 that will submit as virtual groups in Quality Payment Program Year 3 (b)	0	40	40	0	80
Add in: Number of virtual groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 (c)	0	8	8	0	16
Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 (d) = (a) – (b) + (c)	0	3,788	1,501	286	5,575
* Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 2 (e)	0	2,936	1,509	296	4,741
Difference between Year 3 and Year 2 (f) = (d) – (e)	0	852	–8	–10	834

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

The burden estimates associated with submission of quality performance category data have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' work flows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality data codes into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. Further, these burden estimates are based on historical rates of participation in the PQRS program, and the rate of participation in MIPS is expected to differ. In addition, the submission type used to submit MIPS data may also vary from these estimates due to more accurate information being unavailable at this time for this proposed rule.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimate the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our

burden estimates for the claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures.

We estimate an increase in the number of QPs from 100,649 in CY 2018 Quality Payment Program final rule to 120,508 for this proposed rule (82 FR 53908) and since they are excluded from submitting MIPS data, a decrease to our estimated number of respondents by submission and collection type relative to the estimates in the CY 2018 Quality Payment Program final rule (82 FR 53912 through 53915). As noted previously in this section, information collections associated with the Shared Savings Program and the testing, evaluation, and expansion of CMS Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.

Quality Payment Program Identity Management Application Process: The proposed requirements and burden associated with the application process will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2018 Quality Payment Program final rule, the time associated with the Identity Management Application Process was described as "Obtain Account in CMS-Specified Identity Management System" and included in the ICR for Quality Data

Submission by Clinicians and Groups: EHR Submission (82 FR 53914) for a total burden of 54,218 hours (1 hr × 54,218 respondents). After our review of the quality data submission process, we determined the burden associated with the application process (3,741 hours) should be accounted for in a separate ICR. Our per respondent burden estimate remains unchanged at 1 hour per response.

For an individual, group, or third-party to submit MIPS quality, improvement activities, or Promoting Interoperability performance category data using either the log in and upload or the log in and attest submission type or to access feedback reports, the submitter must have a CMS Enterprise Portal user account. Once the user account is created, registration is not required again for future years.

Based on the number of new TINs registered in the 2017 MIPS performance period, we estimate 3,741 eligible clinicians, groups, or third-parties will register for new accounts for the 2019 MIPS performance period. As shown in Table 68 it would take 1 hour at \$89.18/hr for a computer systems analyst (or their equivalent) to obtain an account for the CMS Enterprise Portal. In aggregate we estimate an annual burden of 3,741 hours (3,741 registrations × 1 hr/registration) at a cost of \$333,622 (3,741 hr × \$89.18/hr) or \$89.18 per registration.

TABLE 68—ESTIMATED BURDEN FOR QUALITY PAYMENT PROGRAM IDENTITY MANAGEMENT APPLICATION PROCESS

	Burden estimate
Number of New TINs completing the Identity Management Application Process (a)	3,741

TABLE 68—ESTIMATED BURDEN FOR QUALITY PAYMENT PROGRAM IDENTITY MANAGEMENT APPLICATION PROCESS—Continued

	Burden estimate
Total Hours Per Application (b)	1
Total Annual Hours for completing the Identity Management Application Process (c) = (a) * (b)	3,741
Cost Per Application @ computer systems analyst's labor rate of \$89.18/hr.) (d)	\$89.18
Total Annual Cost for completing the Identity Management Application Process (e) = (a) * (d)	\$333,622

Quality Data Submission by Clinicians: Claims-Based Collection Type: The proposed requirements and burden associated with clinicians' claims-based data submissions will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Table 65, based on 2016 PQRS data and 2017 MIPS eligibility data, we assume that 274,702 individual clinicians will collect and submit quality data via the claims collection type. We continue to anticipate that the claims submission process for MIPS is operationally similar to the way the claims submission process functioned under the PQRS. Specifically, clinicians will need to gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. Clinicians will collect QDCs as additional (optional) line items on the CMS–1500 claim form or the electronic equivalent HIPAA transaction 837–P, approved by OMB under control number 0938–1197. This rule's proposed provisions would not necessitate the revision of either form.

For this CY 2019 Quality Payment Program rule, we are proposing adjustments to the number of respondents based on more recent data and adjustments to our per respondent time estimates so that they correctly align with the number of required measures for which MIPS data must be submitted (6 measures) in comparison to the number of measures previously required under PQRS (9 measures).

The total estimated burden of claims-based submission will vary along with the volume of claims on which the

submission is based. Based on our experience with PQRS, we estimate that the burden for submission of MIPS quality data will range from 0.15 to 7.2 hours per clinician, a reduction from the range of 0.22 to 10.8 hours as set out in the CY 2018 Quality Payment Program final rule (82 FR 53912). In the same rule, the 33 percent reduction in the number of measures (from 9 to 6) was erroneously omitted from our burden calculations; it is reflected in this proposed rule's burden estimates. The wide range of estimates for the time required for a clinician to submit quality measures via claims reflects the wide variation in complexity of submission across different clinician quality measures. As shown in Table 69, we estimate that the cost of quality data submission using claims will range from \$13.38 (0.15 hr × \$89.18/hr) to \$642.10 (7.2 hr × \$89.18/hr). The burden will involve becoming familiar with MIPS data submission requirements. We believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at \$107.38/hr for a practice administrator, 1 hour at \$206.44/hr for a clinician, 1 hour at \$43.96/hr for an LPN/medical assistant, 1 hour at \$89.18/hr for a computer systems analyst, and 1 hour at \$36.98/hr for a billing clerk.

The estimate for reviewing and incorporating measure specifications for the claims collection type is higher than that of QCDRs/Registries or eCQM collection types due to the more manual, and therefore, more burdensome nature of claims measures.

Considering both data submission and start-up requirements, the estimated time (per clinician) ranges from a

minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In this regard the total annual burden ranges from 1,964,119 hours (7.15 hr × 274,702 clinicians) to 3,900,768 hours (14.2 hr × 274,702 clinicians). The estimated annual cost (per clinician) ranges from \$712.08 (\$13.38 + \$322.14 + \$89.18 + \$43.96 + \$36.98 + \$206.44) to a maximum of \$1,340.80 (\$642.10 + \$322.14 + \$89.18 + \$43.96 + \$36.98 + \$206.44). The total annual burden ranges from a minimum of \$195,609,800 (274,702 clinicians × \$712.08) to a maximum of \$368,320,442 (274,702 clinicians × \$1,340.80).

Table 69 summarizes the range of total annual burden associated with clinicians submitting quality data via claims.

Independent of the change in the number of respondents, the change in estimated time per clinician results in a burden adjustment of between –20,853 hours at –\$1,860,081 (278,039 clinicians × –0.075 hr × \$89.18/hr) and –1,000,941 hours at –\$89,261,641 (278,039 clinicians × –3.6 hr × \$89.18/hr). Accounting for the change in the time burden per respondent, the decrease in number of respondents results in a total adjustment of between –23,860 hours at –\$2,376,211 (–3,337 respondents × \$712.08/respondent) and –47,385 hours at –\$4,474,249 (–3,337 respondents × \$1,340.80/respondent). When these two adjustments are combined, the net adjustment ranges between –44,713 (–20,853 – 23,860) hours at –\$4,236,292 (–\$1,860,081 – \$2,376,211) and –1,048,326 (–1,000,941 – 47,385) hours at –\$93,735,890 (–\$89,261,641 – \$4,474,249).

TABLE 69—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS USING THE CLAIMS COLLECTION TYPE

	Minimum burden	Median burden	Maximum burden estimate
Number of Clinicians (a)	274,702	274,702	274,702
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2
Number of Hours Practice Administrator Review Measure Specifications (c)	3	3	3
Number of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1

TABLE 69—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY:—Continued
CLINICIANS USING THE CLAIMS COLLECTION TYPE

	Minimum burden	Median burden	Maximum burden estimate
Number of Hours LPN Review Measure Specifications (e)	1	1	1
Number of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
Number of Hours Clinician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2
Total Annual Hours (i) = (a) * (h)	1,964,119	2,211,351	3,900,768
Cost to Submit Quality Data (@ computer systems analyst's labor rate of \$89.18/hr.) (j)	\$13.38	\$93.64	\$642.10
Cost to Review Measure Specifications (@ practice administrator's labor rate of \$107.38/hr.) (k)	\$322.14	\$322.14	\$322.14
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of \$89.18/hr.) (l)	\$89.18	\$89.18	\$89.18
Cost to Review Measure Specifications (@ LPN's labor rate of \$43.96/hr.) (m)	\$43.96	\$43.96	\$43.96
Cost to Review Measure Specifications (@ billing clerk's labor rate of \$36.98/hr.) (n)	\$36.98	\$36.98	\$36.98
Cost to Review Measure Specifications (@ physician's labor rate of \$206.44/hr.) (o)	\$206.44	\$206.44	\$206.44
Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	\$712.08	\$792.34	\$1,340.80
Total Annual Cost (q) = (a) * (p)	\$195,609,800	\$217,657,383	\$368,320,442

Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types: This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to this quality data submission. However, we are proposing adjustments to the number of respondents based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 65, 66, and 67 and based on the 2016 PQRS data and 2017 MIPS eligibility data, we assume that 267,736 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. Of these, we expect 103,268 clinicians, as shown in Table 66, to submit as individuals and 3,788 groups, as shown in Table 67, are expected to submit on behalf of the remaining 164,468 clinicians. Given that the number of measures required is the same for clinicians and groups, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is

participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party vendor to submit the data to us on the clinician's or group's behalf.

We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS submission requirements and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data total 9.083 hours at \$858.86. This consists of 3 hours at \$89.18/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at \$107.38/hr for a practice administrator, 1 hour at \$89.18/hr for a computer systems analyst, 1 hour at

\$43.96/hr for a LPN/medical assistant, 1 hour at \$36.98/hr for a billing clerk, and 1 hour at \$206.44/hr for a clinician to review measure specifications. Additionally, clinicians and groups will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) per clinician or group (respondent) for a cost of \$7.40 (0.083 hr × \$89.18/hr for a computer systems analyst).

In aggregate we estimate an annual burden of 972,390 hours (9.083 hr/response × 107,056 groups plus clinicians submitting as individuals) at a cost of \$92,738,331 (107,056 responses × \$866.26/response). The decrease in number of respondents results in a total adjustment of –1,462 hours at –\$139,467 (–161 respondents × \$866.26/respondent). Based on these assumptions, we have estimated in Table 70 the burden for these submissions.

TABLE 70—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE MIPS CQM/QCDR COLLECTION TYPE

	Burden estimate
Number of clinicians submitting as individuals (a)	103,268
Number of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	3,788
Number of Respondents (groups plus clinicians submitting as individuals) (c) = (a) + (b)	107,056
Hours Per Respondent to Report Quality Data (d)	3
Number of Hours Practice Administrator Review Measure Specifications (e)	2

TABLE 70—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE MIPS CQM/QCQR COLLECTION TYPE—Continued

	Burden estimate
Number of Hours Computer Systems Analyst Review Measure Specifications (f)	1
Number of Hours LPN Review Measure Specifications (g)	1
Number of Hours Billing Clerk Review Measure Specifications (h)	1
Number of Hours Clinician Review Measure Specifications (i)	1
Number of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k) = (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c) * (k)	972,390
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of \$89.18/hr.) (m)	\$267.54
Cost to Review Measure Specifications (@ practice administrator's labor rate of \$107.38/hr.) (n)	\$214.76
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of \$89.18/hr.) (o) ...	\$89.18
Cost LPN Review Measure Specifications (@ LPN's labor rate of \$43.96/hr.) (p)	\$43.96
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of \$36.98/hr.) (q)	\$36.98
Cost Clinician Review Measure Specifications (@ physician's labor rate of \$206.44/hr.) (r)	\$206.44
Cost for Respondent to Authorize Qualified Registry/QCQR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of \$89.18/hr.) (s)	\$7.40
Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	\$866.26
Total Annual Cost (u) = (c) * (t)	\$92,738,331

Quality Data Submission by Clinicians and Groups: eCQM Collection Type: This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to this quality data submission. However, we are proposing adjustments to the number of respondents based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 65, 66, and 67, based on 2016 PQRS data and 2017 MIPS eligibility data, we assume that 129,188 clinicians will elect to use the eCQM collection type; 52,028 clinicians are expected to submit eQMs as individuals; and 1,501 groups are expected to submit eQMs on behalf of 77,160 clinicians. We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

In the CY 2018 Quality Payment Program final rule, the time required for users to obtain an account for the CMS Enterprise Portal was included in this Quality Data Submission by Clinicians and Groups: eCQM Collection Type ICR (82 FR 53914). However, in this CY 2019 Quality Payment Program rule, we are proposing a separate ICR for this activity (now described as the Quality Payment Program Identity Management Application Process; see Table 68) and to reduce (by 1 hour) our per respondent

burden estimate for this ICR commensurately. We are also proposing an adjustment to the number of respondents based on more recent data.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize an eCQM data submission vendor to submit the data to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eQMs, select the appropriate quality measures, extract the necessary clinical data from their eCQM, and submit the necessary data to the CMS-designated clinical data warehouse or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use an eCQM data submission vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their EHR and submitting the necessary data to the CMS-designated clinical data warehouse.

We continue to estimate that it will take no more than 2 hours at \$89.18/hr for a computer systems analyst to submit the actual data file. The burden

will also involve becoming familiar with MIPS submission. In this regard we estimate it would take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at \$107.38/hr for a practice administrator, 1 hour at \$206.44/hr for a clinician, 1 hour at \$89.18/hr for a computer systems analyst, 1 hour at \$43.96/hr for a LPN/medical assistant, and 1 hour at \$36.98/hr for a billing clerk.

In aggregate we estimate an annual burden of 428,232 hours (8 hr × 53,529 groups and clinicians submitting as individuals) at a cost of \$41,200,201 (53,529 responses × \$769.68/response) (see Table 71).

Independent of the change in the number of respondents, removing the time burden associated with completing the Quality Payment Program Identity Management Application Process results in an adjustment to the total burden of –54,218 hours and –\$4,835,161 (54,218 respondents × –1 hr × \$89.18/hr). Accounting for the change in the per respondent time estimate, the decrease in number of respondents results in a total adjustment of –5,512 hours at –\$530,309 (–689 respondents × \$769.68/respondent). When these two adjustments are combined, the net adjustment is –59,730 (–54,218 – 5,512) hours at –\$5,365,470 (–\$4,835,161 – \$530,309).

TABLE 71—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (SUBMITTING INDIVIDUALLY OR AS PART OF A GROUP) USING THE eCQM COLLECTION TYPE

	Burden estimate
Number of clinicians submitting as individuals (a)	52,028
Number of Groups submitting via EHR on behalf of individual clinicians (b)	1,501
Number of Respondents (groups and clinicians submitting as individuals) (c) = (a) + (b)	53,529
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
Number of Hours Practice Administrator Review Measure Specifications (e)	2
Number of Hours Computer Systems Analyst Review Measure Specifications (f)	1
Number of Hours LPN Review Measure Specifications (g)	1
Number of Hours Billing Clerk Review Measure Specifications (h)	1
Number of Hours Clinicians Review Measure Specifications (i)	1
Annual Hours per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i).	
Total Annual Hours (k) = (c) * (j)	428,232
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of \$88.10/hr.) (l)	\$178.36
Cost to Review Measure Specifications (@ practice administrator's labor rate of \$105.16/hr.) (m)	\$214.76
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of \$88.10/hr.) (n)	\$89.18
Cost to Review Measure Specifications (@ LPN's labor rate of \$43.12/hr.) (o)	\$43.96
Cost to Review Measure Specifications (@ clerk's labor rate of \$36.12/hr.) (p)	\$36.98
Cost to D21Review Measure Specifications (@ physician's labor rate of \$202.08/hr.) (q)	\$206.44
Total Cost Per Respondent (r) = (l) + (m) + (n) + (o) + (p) + (q)	\$769.68
Total Annual Cost (s) = (c) * (r)	\$41,200,201

Quality Data Submission via CMS Web Interface: The proposed requirements and burden associated with this data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As discussed in section III.H.3.h.(2)(a)(ii)(A)(bb) of this rule, we are proposing a 40 percent reduction in the number of measures (from 15 to 9 measures) for which clinicians are required to submit quality data via the CMS Web Interface. To account for the decrease in measures, we are also proposing to decrease our per respondent time estimate.

We assume that 286 groups will submit quality data via the CMS Web Interface based on the number of groups who submitted quality data via the CMS Web Interface during the 2018 MIPS performance period. This is a decrease of 10 groups from the currently approved number provided in the CY 2018 Quality Payment Program final rule (82 FR 53915) due to receipt of more current data. We anticipate that approximately 91,757 clinicians will be represented.

The burden associated with the group submission requirements is the time and effort associated with submitting data on a sample of the organization's

beneficiaries that is prepopulated in the CMS Web Interface. In the CY 2018 Quality Payment Program final rule, we estimated that it would take, on average, 74 hours for each group to submit quality measures data via the CMS Web Interface (82 FR 53915). Of those hours, approximately half (or 37 hr) are unaffected by the number of required measures while the other half (37 hr) are affected proportionately by the number of required measures (60 percent of 37 hr is adjusted to 22.2 hr). Accounting for the proposed reduction in required measures, our revised estimate for the time to submit data via the CMS Web Interface for the 2019 MIPS performance period is 59.2 hours (37 hr + 22.2 hr), a reduction of 14.8 hours or 40 percent of the currently approved 37 hour time estimate. Considering only the time which varies based on the number of required measures, the process of entering or uploading data requires approximately 2.5 hours of a computer systems analyst's time per measure (22.2 hr/9 measures). Our estimate for submission includes the time needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries, submit the data (we will partially pre-populate the CMS Web Interface with claims data from

their Medicare Part A and B beneficiaries). The patient data either can be manually entered, uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT, or submitted directly. Each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248) for each measure. In aggregate we estimate an annual burden of 16,931 hours (286 groups × 59.2 hr) at a cost of \$1,509,907 (16,931 hr × \$89.18/hr).

Independent of the change in the number of respondents, the decrease in total burden resulting from the decrease in required measures is –4,381 hours at –\$390,679 (296 groups × –14.8 hr × \$89.18/hr). Accounting for the decrease in total time, the decrease in number of respondents results in a total adjustment of –592 hours at –\$52,794 (–10 respondents × \$5,279/respondent). When these adjustments are combined, the net adjustment is –4,973 (–4,381 – 592) hours at –\$443,473 (–\$390,679 – \$52,794).

Based on the assumptions discussed in this section, Table 72 summarizes the burden for groups submitting to MIPS via the CMS Web Interface.

TABLE 72—ESTIMATED BURDEN FOR QUALITY DATA SUBMISSION VIA THE CMS WEB INTERFACE

	Burden estimate
Number of Eligible Group Practices (a)	286

TABLE 72—ESTIMATED BURDEN FOR QUALITY DATA SUBMISSION VIA THE CMS WEB INTERFACE—Continued

	Burden estimate
Total Annual Hours Per Group to Submit (b)	59.2
Total Annual Hours (c) = (a) * (b)	16,931
Cost Per Group to Report (@ computer systems analyst's labor rate of \$89.18/hr.) (d)	\$5,279
Total Annual Cost (e) = (a) * (d)	\$1,509,907

Beneficiary Responses to CAHPS for MIPS Survey: This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the survey. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1222 (CMS–10450).

In this CY 2019 Quality Payment Program rule, we are proposing adjustments to the number of groups electing to report on the CAHPS for MIPS survey as well as the average number of beneficiaries per group based on more recent data.

Under MIPS, groups of 25 or more clinicians can elect to contract with a CMS-approved survey vendor and use the CAHPS for MIPS survey as one of their 6 required quality measures. Beneficiaries that choose to respond to the CAHPS for MIPS survey will experience burden.

The usual practice in estimating the burden on public respondents to surveys such as CAHPS is to assume that respondent time is valued, on average, at civilian wage rates. As explained in section V.A. of this proposed rule, BLS data sets out an

average hourly wage for civilians in all occupations to be \$24.34/hr. Although most Medicare beneficiaries are retired, we believe that their time value is unlikely to depart significantly from prior earnings expense, and we have used the average hourly wage to compute our cost estimate for the beneficiaries' time.

For the 2019 MIPS performance period, we assume that 241 groups will elect to report on the CAHPS for MIPS survey, which is equal to the number of groups participating in CAHPS for MIPS for the 2017 MIPS performance period and a decrease from the 461 groups currently approved by OMB. Table 73 shows the estimated annual burden for beneficiaries to participate in the CAHPS for MIPS Survey. Based on the number of complete and partially complete surveys for groups participating in CAHPS for MIPS survey administration for the 2017 MIPS performance period, we assume that an average of 273 beneficiaries will respond per group for the 2019 MIPS performance period. Therefore, the CAHPS for MIPS survey will be administered to approximately 65,793 beneficiaries per year (241 groups × an average of 273 beneficiaries per group responding). This is an adjustment to

our currently approved 132,307 beneficiary estimate.

The CAHPS for MIPS survey that will be administered in the 2019 MIPS performance period is unchanged from the survey administered in the 2018 MIPS performance period. In that regard we continue to estimate an average administration time of 12.9 minutes (or 0.215 hr) at a pace of 4.5 items per minute for the English version of the survey. For the Spanish version, we estimate an average administration time of 15.5 minutes (assuming 20 percent more words in the Spanish translation). However, since less than 1 percent of surveys were administered in Spanish for reporting year 2016, our burden estimate reflects the time for administering the English version of the survey.

Given that we expect approximately 65,793 respondents, we estimate an annual burden of 14,145 hours (65,793 respondents × 0.215 hr/respondent) at a cost of \$344,289 (14,145 hr × \$24.34/hr).

The decrease in the number of beneficiaries responding to the CAHPS for MIPS survey results in an adjustment to the total time burden of – 14,301 hours and – \$348,087 (– 66,514 beneficiaries × 0.215 hr × \$24.34/hr).

TABLE 73—ESTIMATED BURDEN FOR BENEFICIARY PARTICIPATION IN CAHPS FOR MIPS SURVEY

	Burden estimate
Number of Eligible Group Practices Administering CAHPS for MIPS (a)	241
Number of Beneficiaries Per Group Responding to Survey (b)	273
Number of Total Beneficiary Respondents (c) = (a) * (b)	65,793
Number of Hours Per Beneficiary Respondent (d)	0.215
Cost (@ labor rate of \$24.34/hr.) (e)	\$24.34/hr
Total Annual Hours (f) = (c) * (d)	14,145
Total Annual Cost for Beneficiaries Responding to CAHPS for MIPS (g) = (c) * (e)	\$344,289

Group Registration for CMS Web Interface: This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the group registration. However, we are proposing adjustments to our currently approved

burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1222 (CMS–10450).

In this CY 2019 Quality Payment Program rule, we are proposing to adjust

the number of respondents based on more recent data and an adjustment to our per response time estimate based on our review of the currently approved estimates against the existing registration process.

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an on-line registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 74 we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at \$89.18/hr for a computer systems analyst (or their equivalent) to register the group. Although the registration process remains unchanged from the CY 2018 Quality Payment Program final rule, a review of the steps

required for registration warranted a reduction of 0.75 hours in estimated burden per group (82 FR 53917).

We assume that approximately 67 groups will elect to use the CMS Web Interface submission type for the first time during the 2019 MIPS performance period based on the number of new registrations received during the CY 2018 registration period; an increase of 57 compared to the number of groups currently approved by OMB under control number 0938–1314 (CMS–10621). In aggregate we estimate a burden of 16.75 hours (67 new registrations \times 0.25 hr/registration) at a cost of \$1,494 (16.75 hr \times \$89.18/hr).

Independent of the decrease in time burden per group, the increase in the number of groups registering to submit MIPS data via the CMS Web Interface results in an adjustment to the total time burden of 57 hours at \$5,083 (57 groups \times 1 hr \times \$89.18/hr). Accounting for the increase in the number of groups, the decrease in time burden per group to register results in an adjustment to the total burden of –50.25 hours at –\$4,481 (67 groups \times –0.75 hrs \times \$89.18/hr). When these adjustments are combined, the net adjustment is 6.75 hours (57 – 50.25) at \$602 (\$5,083 – \$4,481).

TABLE 74—ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CMS WEB INTERFACE

	Burden estimate
Number of New Groups Registering for CMS Web Interface (a)	67
Annual Hours Per Group (b)	0.25
Total Annual Hours (c) = (a) * (b)	16.75
Labor Rate to Register for CMS Web Interface @ computer systems analyst's labor rate) (d)	\$89.18/hr
Total Annual Cost for CMS Web Interface Group Registration (e) = (a) * (d)	\$1,494

Group Registration for CAHPS for MIPS Survey: This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the group registration. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1222 (CMS–10450).

In this CY 2019 Quality Payment Program rule, we are proposing to adjust our currently approved number of respondents based on more recent data and adjust our per respondent time estimate based on our review of the current burden estimates against the existing registration process.

Under MIPS, the CAHPS for MIPS survey counts for 1 measure toward the MIPS quality performance category and, as a patient experience measure, it also fulfills the requirement to submit at least one high priority measure in the absence of an applicable outcome measure. Groups that wish to administer the CAHPS for MIPS survey must

register by June of the applicable 12-month performance period, and electronically notify CMS of which vendor they have selected to administer the survey on their behalf. For the 2019 MIPS performance period, we assume that 454 groups will enroll in the MIPS for CAHPS survey based on the number of groups which elected to register during the CY 2017 registration period; a decrease of 7 compared to the number of groups currently approved by OMB under the aforementioned control number (82 FR 53917).

As shown in Table 75, we assume that the staff involved in the group registration for CAHPS for MIPS Survey will mainly be computer systems analysts (or their equivalent) who have an average labor cost of \$89.18/hr. We assume the CAHPS for MIPS Survey registration burden consists of 0.25 hours to register for the survey as well as 0.5 hours to select the CAHPS for MIPS Survey vendor that will be used and electronically notify CMS of their selection. In this regard the total time for CAHPS for MIPS registration is 0.75 hours. Although the registration process

remains unchanged from the CY 2018 Quality Payment Program final rule, after we reviewed the steps required for registration more thoroughly, we believe that the burden was less than we had originally estimated. In that regard we propose to reduce the estimated burden from 1.5 hours to 0.75 hours per respondent

In aggregate we estimate an annual burden of 340.50 hours (454 groups \times 0.75 hr per group) at a cost of \$30,366 (340.50 hr \times \$89.18/hr).

Independent of the change in time per group, the decrease in the number of groups registering results in an adjustment to the total burden of –10.5 hours at –\$936 (–7 groups \times 1.5 hrs \times \$89.18/hr). Accounting for the decrease in the number of groups registering, the decrease in time per group to register results in an adjustment to the total burden of –340.5 hours at –\$30,366 (454 groups \times –0.75 hr \times \$89.18/hr). When these adjustments are combined, the net adjustment is –351 hours (–10.5 – 340.5) at –\$31,302 (–\$936 – \$30,366).

TABLE 75—ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CAHPS FOR MIPS SURVEY

	Burden estimate
Number of Groups Registering for CAHPS (a)	454
Total Annual Hours for CAHPS Registration (b)	0.75
Total Annual Hours for CAHPS Registration (c) = (a) * (b)	340.5

TABLE 75—ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CAHPS FOR MIPS SURVEY—Continued

	Burden estimate
Labor Rate to Register for CAHPS (computer systems analyst) (d)	\$89.18/hr
Total Annual Cost for CAHPS Registration (e) = (a) * (d)	\$30,366

9. Quality Payment Program ICRs Regarding the Nomination of Quality Measures

This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the group registration. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. We are also proposing to account for burden associated with policies that have been finalized but whose burden were erroneously excluded from our estimates. The new and adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As discussed in section III.H.3.h.(2)(b)(i) of this proposed rule, quality measures are selected annually through a call for quality measures under consideration, with a final list of quality measures being published in the **Federal Register** by November 1 of each year. Under section 1848(q)(2)(D)(ii) of the Act, the Secretary must solicit a “Call for Quality Measures” each year. Specifically, the Secretary must request that eligible clinician organizations and other relevant stakeholders identify and submit quality measures to be considered for selection in the annual list of MIPS quality measures, as well as updates to the measures. Under section 1848(q)(2)(D)(ii) of the Act, eligible clinician organizations are professional organizations as defined by nationally recognized specialty boards of certification or equivalent certification boards.

As we described in the CY 2017 Quality Payment Program final rule (81 FR 77137), we will accept quality measures submissions at any time, but only measures submitted during the timeframe provided by us through the pre-rulemaking process of each year will

be considered for inclusion in the annual list of MIPS quality measures for the performance period beginning 2 years after the measure is submitted. This process is consistent with the pre-rulemaking process and the annual call for measures, which are further described at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html>.

To identify and submit a quality measure, eligible clinician organizations and other relevant stakeholders use a one-page online form that requests information on background, gap analysis which includes evidence for the measure, reliability validity, endorsement and a summary which includes how the proposed measure relates to the Quality Payment Program and the rationale for the measure. In addition, proposed measures must be accompanied by a completed Peer Review Journal Article form.

As shown in Table 76, we estimate that approximately 140 organizations, including clinicians, CEHRT developers, and vendors, will submit measures for the Call for Quality Measures process; an increase of 100 compared to the number of organizations currently approved by OMB. In keeping with the focus on clinicians as the primary source for recommending new quality measures, we are using practice administrators and clinician time for our burden estimates. We also estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at \$107.38/hr for a practice administrator to make a strategic decision to nominate and submit a measure and 0.2 hours at \$206.44/hr for clinician review time.

The 0.5 hour estimate assumes that submitters will have the necessary information to complete the nomination

form readily available, which we believe is a reasonable assumption.

Additionally, some submitters familiar with the process or who are submitting multiple measures may require significantly less time, while other submitters may require more if the opposite is true; on average we believe 0.5 hours is a reasonable average across all submitters.

Consistent with the CY 2017 Quality Payment Program final rule, we also estimate it will take 4 hours at \$206.44/hr for a clinician (or equivalent) to complete the Peer Review Journal Article Form (81 FR 77153 through 77155). This assumes that measure information is available and testing is complete in order to have the necessary information to complete the form, which we believe is a reasonable assumption. While the requirement for completing the Peer Review Journal Article was previously included in the CY 2017 Quality Payment Program final rule, the time required for completing the form was erroneously excluded from our burden estimates.

As shown in Table 76, in aggregate we estimate an annual burden of 630 hours (140 organizations × 4.5 hr/response) at a cost of \$125,896 (140 × [(0.3 hr × \$107.38/hr) + (4.2 hr × \$206.44/hr)]).

Independent of the change in time per organization, the change in the number of organizations nominating new quality measures results in an adjustment of 50 hours at \$7,350 (100 organizations × [(0.3 hr × \$107.38/hr) + (0.2 hr × \$206.44/hr)]). When accounting for the change in respondents, the change in burden to nominate a quality measure results in an adjustment of 560 hours at \$115,606 (140 organizations × 4 hr × \$206.44/hr). When these adjustments are combined, the total adjustment is 610 hours (560 + 50) at \$122,956 (\$7,350 + \$115,606).

TABLE 76—ESTIMATED BURDEN FOR CALL FOR QUALITY MEASURES

	Burden estimate
Number of Organizations Nominating New Quality Measures (a)	140
Number of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.30
Number of Hours Per Clinician to Identify Measure (c)	0.20
Number of Hours Per Clinician to Complete Peer Review Article Form (d)	4.00

TABLE 76—ESTIMATED BURDEN FOR CALL FOR QUALITY MEASURES—Continued

	Burden estimate
Annual Hours Per Response (e) = (b) + (c) + (d)	4.50
Total Annual Hours (f) = (a) * (e)	630
Cost to Identify and Submit Measure (@ practice administrator's labor rate of \$107.38/hr.) (g)	\$32.21
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ physician's labor rate of \$206.44/hr.) (h)	\$867.05
Total Annual Cost Per Respondent (i) = (g) + (h)	\$899.26
Total Annual Cost (j) = (a) * (i)	\$125,896

10. Quality Payment Program ICRs Regarding Promoting Interoperability Data (§ 414.1375)

The proposed requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

For the 2019 MIPS performance period, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. We have worked to further align the Promoting Interoperability performance category with other MIPS performance categories. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category which is not available for the quality performance category, we anticipate that most organizations will use the same data submission type for the both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. Hence, the following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. While this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis and decisions are expected to be made for the program as a whole.

Promoting Interoperability Reweighting Applications: As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an

application requesting a zero percent weighting for the Promoting Interoperability performance category in the following circumstances:

Insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT, and decertified EHR technology (81 FR 77240 through 77243 and 82 FR 53680 through 53686).

Table 77 summarizes the burden for clinicians to apply for reweighting the Promoting Interoperability performance category to zero percent due to a significant hardship exception (including a significant hardship exception for small practices) or as a result of a decertification of an EHR. Participation data for the 2017 MIPS performance period was unavailable in time for this proposed rule. However, assuming that the actual participation data for the 2017 MIPS performance period is available in time to meet our final rule's publication schedule, we will use this data and revise our estimates in that rule. As a result, we assume 87,211 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship (including small practices) or EHR decertification through the Quality Payment Program based on 2016 data from the Medicare EHR Incentive Program and the first 2019 payment year MIPS eligibility and special status file. We estimate that 5,941 respondents (eligible clinicians or groups) will submit a request for reweighting the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR. An additional 81,270 respondents will submit a request for

reweighting the Promoting Interoperability performance category to zero percent as a small practice experiencing a significant hardship. In total, this represents an increase of 46,566 from the number of respondents currently approved by OMB.

The application to request a reweighting to zero percent for the Promoting Interoperability performance category is a short online form that requires identifying the type of hardship experienced or whether decertification of an EHR has occurred and a description of how the circumstances impair the ability to submit Promoting Interoperability data, as well as some proof of circumstances beyond the clinician's control. We estimate it would take 0.25 hours at \$89.18/hr for a computer system analyst to submit the application. This is a reduction from the 0.5 hours estimated in the CY 2018 Quality Payment Program final rule due to a revised assessment of the application process (82 FR 53918). As shown in Table 77, in aggregate we estimate an annual burden of 21,803 hours (87,211 applications × 0.25 hr/application) at a cost of \$1,944,369 (21,803 hr × \$89.18/hr).

Independent of the change to the number of respondents, the decrease in the amount of time to submit a reweighting application results in an adjustment of – 10,161.25 hours at – \$906,180 (40,645 respondents × – 0.25 hr × \$89.18/hr). Accounting for the decrease in time per respondent, the increase in the number of respondents submitting reweighting applications results in an adjustment of 11,641.5 hours at \$1,038,188 (46,566 respondents × 0.25 hr × \$89.18/hr). When these adjustments are combined, the total adjustment is 1,480.25 hours (11,641.5 – 10,161.25) at \$132,008 (\$1,038,188 – \$906,180).

TABLE 77—ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY REWEIGHTING APPLICATIONS

	Burden estimate
Number of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions (a)	5,941
Number of Eligible Clinicians or Groups Applying Due to Significant Hardship as Small Practice (b)	81,270
Total Respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c)	87,211
Hours Per Applicant per application submission (d)	0.25
Total Annual Hours (e) = (a) * (c)	21,802.75
Labor Rate for a computer systems analyst (f)	\$89.18/hr
Total Annual Cost (g) = (a) * (f)	\$1,944,369

Submitting Promoting Interoperability Data: In this CY 2019 Quality Payment Program proposed rule, we are proposing an adjustment to the number of respondents based on more recent data and a decrease to the per respondent time estimate due to our proposed net reduction of 3 measures (6 removed measures and 3 new measures) for which clinicians are required to submit data, as discussed in section III.H.3.h.(5)(f) of this proposed rule.

A variety of organizations will submit Promoting Interoperability data on behalf of clinicians. Clinicians not participating in a MIPS APM may submit data as individuals or as part of a group. In the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260, 77262 through 77264), we established that eligible clinicians in MIPS APMS other than the Shared Savings Program may submit data for the Promoting Interoperability performance category as individuals or as part of a group, whereas eligible clinicians participating in the Shared Savings Program are limited to submitting data through the ACO participant TIN. In section III.H.3.h.(6)(c)(ii) of this proposed rule, we propose to extend this flexibility to allow for both individual and group reporting by eligible clinicians participating in the Shared Savings Program.

Because group TINs in APM Entities are able to submit Promoting

Interoperability data to fulfill the requirements of submitting to MIPS, we have included MIPS APMs groups in our burden estimates for the Promoting Interoperability performance category. Consistent with the list of APMs that are MIPS APMs on the Quality Payment Program website,⁴⁵ we assume that 3 MIPS APMs that do not also qualify as Advanced APMs will operate in the 2019 MIPS performance period: Track 1 of the Shared Savings Program, CEC (one-sided risk arrangement), and the OCM (one-sided risk arrangement). Further, we assume that group TINs will submit Promoting Interoperability data on behalf of partial QPs that elect to participate in MIPS. We plan to revisit these assumptions as when we receive data submitted for the 2017 MIPS performance period.

As shown in Table 78, based on data from the 2016 Medicare and Medicaid EHR Incentive Programs, the 2016 PQRS data, and 2017 MIPS eligibility data, we estimate that 50,878 individual MIPS eligible clinicians and 2,998 groups will submit Promoting Interoperability data. These estimates reflect that under the policies in the CY 2017 Quality Payment Program final rule and in the CY 2018 Quality Payment Program final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of the Promoting Interoperability performance category to zero percent, including MIPS eligible

clinicians that are hospital-based, ambulatory surgical center-based, non-patient facing clinicians, physician assistants, nurse practitioners, clinician nurse specialists, and certified registered nurse anesthetists (81 FR 77238 through 77245 and 82 FR 53680 through 53687). As discussed in section III.H.3.h.(5)(h)(ii) of this proposed rule, starting with the 2021 MIPS payment year, we are proposing to automatically reweight the Promoting Interoperability performance category for clinician types new to MIPS: Physical therapists, occupational therapists, clinical social workers, and clinical psychologists. These estimates also account for the reweighting exceptions finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, including for MIPS eligible clinicians in small practices, as well as exceptions due to decertification of an EHR.

Further, we anticipate that the 460 Shared Savings Program Track 1 ACOs will submit data at the ACO participant TIN-level, for a total of 13,537 group TINs. We anticipate that the three APM Entities electing the one-sided track in the CEC model will submit data at the group TIN-level, for a total of 17 group TINs submitting data. And finally, we anticipate that the 192 APM Entities in the OCM (one-sided risk arrangement) will submit data at APM Entity level. The total estimated number of respondents is estimated at 67,622.

TABLE 78—ESTIMATED NUMBER OF RESPONDENTS TO SUBMIT PROMOTING INTEROPERABILITY PERFORMANCE DATA ON BEHALF OF CLINICIANS

	Number of respondents
Number of individual clinicians to submit Promoting Interoperability (a)	50,878
Number of groups to submit Promoting Interoperability (b)	2,998
Shared Savings Program ACO Group TINs (c)	13,537
CEC one-sided risk track participants ⁴⁶ (d)	17
OCM one-sided risk arrangement Group TINs (e)	192

⁴⁵ <https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Comprehensive-List-of-APMs.pdf>.

TABLE 78—ESTIMATED NUMBER OF RESPONDENTS TO SUBMIT PROMOTING INTEROPERABILITY PERFORMANCE DATA ON BEHALF OF CLINICIANS—Continued

	Number of respondents
Total (f) = (a) + (b) + (c) + (d) + (e)	67,622

While we estimate that 67,622 respondents will be submitting data under the Promoting Interoperability performance category, this reduction of 150,593 respondents from the currently approved total of 218,215 is a result of more accurate estimation of the number of hospital-based MIPS eligible clinicians, clinicians in small practices, and the number of group TINs submitting for MIPS APMs; and also accounting for respondents which may submit data via two or more submission or collection types and would thus be double-counted otherwise.

In the CY 2018 Quality Payment Program final rule we estimated it takes 3 hours for a computer system analyst to collect and submit Promoting Interoperability performance category

data (82 FR 53920). For this proposed rule, we estimate the time required to submit such data should be reduced by 20 minutes to 2.67 hours due to our proposal to reduce the number of measures for which clinicians are required to submit data, as discussed in section III.H.3.h.(5)(f) of this proposed rule. As shown in Table 79, the total time for an organization to submit data on the specified Promoting Interoperability objectives and measures is estimated to be 180,325 hours (67,622 respondents × 2.67 incremental hours for a computer analyst's time above and beyond the clinician, practice manager, and computer system's analyst time required to submit quality data) at a cost of \$16,081,413 (180,325 hr × \$89.18/hr).

Independent of the change in the number of respondents, the reduction in estimated time to submit Promoting Interoperability data results in a decrease in burden of – 72,738.33 hours at – \$6,486,805 (218,215 respondents × – 0.33 hr × \$89.18/hr). Accounting for the decreased per respondent time, the decrease in the number of respondents results in an adjustment to the total burden of – 401,581.33 hours at – \$35,813,023 (– 150,593 respondents × 2.67 hrs × \$89.18/hr). When these adjustments are combined, the total adjustment is – 474,319.67 hours (– 72,738.33 – 401,581.33) at – \$42,299,828 (– \$6,486,805 – \$35,813,023).

TABLE 79—ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY DATA SUBMISSION

	Burden estimate
Number of respondents submitting Promoting Interoperability data on behalf of clinicians (a)	67,622
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a) * (b)	180,325
Labor rate for a computer systems analyst to submit Promoting Interoperability data/hr.) (d)	\$89.18/hr
Total Annual Cost (e) = (a) * (d)	\$16,081,413

11. Quality Payment Program ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the nomination of Promoting Interoperability measures. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Consistent with our requests for stakeholder input on quality measures and improvement activities, we are also requesting potential measures for the Promoting Interoperability performance

category that measure patient outcomes, emphasize patient safety, support improvement activities and the quality performance category, and build on the advanced use of CEHRT using 2015 Edition standards and certification criteria. Promoting Interoperability measures may be submitted via a designated submission form that includes the measure description, measure type (if applicable), reporting requirement, and CEHRT functionality used (if applicable).

We estimate 47 organizations will submit Promoting Interoperability measures, based on the number of organizations submitting measures during the CY 2017 nomination period. This is an increase of 7 from the

estimate currently approved by OMB under the aforementioned control number. We estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at \$107.38/hr for a practice administrator to make a strategic decision to nominate that activity and submit an activity to us via email and 0.2 hours at \$206.44/hr for a clinician to review the nomination. As shown in Table 80, in aggregate we estimate an annual burden of 235 hours (47 organizations × 0.5 hr/response) at a cost of \$3,455 (47 × [(0.3 hr × \$107.38/hr) + (0.2 hr × \$206.44/hr)]). The increase in the number of respondents results in an adjustment of 3.5 hours and \$514.50 (7 respondents × 0.5 hrs × \$73.50 per respondent).

⁴⁶ The 3 CEC APM Entities reflected in the burden estimate are the non-large dialysis organizations participating in the one-sided risk track.

TABLE 80—ESTIMATED BURDEN FOR CALL FOR PROMOTING INTEROPERABILITY MEASURES

	Burden estimate
Number of Organizations Nominating New Promoting Interoperability Measures (a)	47
Number of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.30
Number of Hours Per Clinician to Identify Measure (c)	0.20
Annual Hours Per Respondent (d) = (b) + (c)	0.50
Total Annual Hours (e) = (a) * (d)	23.50
Cost to Identify and Submit Measure (@practice administrator's labor rate of \$107.38/hr.) (f)	\$32.21
Cost to Identify Improvement Measure (@ physician's labor rate of \$206.44/hr.) (g)	\$41.29
Total Annual Cost Per Respondent (h) = (f) + (g)	\$73.50
Total Annual Cost (i) = (a) * (h)	\$3,455

12. Quality Payment Program ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

The proposed requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77511 through 77512) and the CY 2018 Quality Payment Program final rule (82 FR 53920 through 53922) for our previous burden estimates for improvement activities under the Quality Payment Program.

The CY 2018 Quality Payment Program final rule provides: (1) That for activities that are performed for at least a continuous 90 days during the performance period, MIPS eligible clinicians must submit a “yes” response for activities within the Improvement Activities Inventory (82 FR 53651); (2) that the term “recognized” is accepted as equivalent to the term “certified” when referring to the requirements for a patient-centered medical home and would receive full credit for the improvement activities performance category (82 FR 53649); and (3) that for the 2020 MIPS payment year and future years, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice (82 FR 53655).

In the CY 2017 Quality Payment Program final rule, we describe how we determine MIPS APM scores (81 FR 77185). We compare the requirements of the specific MIPS APM with the list of

activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77817 through 77831). If, by our assessment, the MIPS APM does not receive the maximum improvement activities performance category score, then the APM Entity can submit additional improvement activities, although, as we noted, we anticipate that MIPS APMs in the 2019 MIPS performance period will not need to submit additional improvement activities as the models will already meet the maximum improvement activities performance category score (81 FR 77185).

A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. For clinicians who are not part of APMs, we assume that clinicians submitting quality data as part of a group through direct, log in and upload, and CMS Web Interface submission types will also submit improvement activities data. In the CY 2017 Quality Payment Program final rule (81 FR 77264), APM Entities only need to report improvement activities data if the CMS-assigned improvement activities score is below the maximum improvement activities score. Our CY 2018 Quality Payment Program final rule burden estimates assumed that all APM Entities will receive the maximum CMS-assigned improvement activities score (82 FR 53921 through 53922).

As represented in Table 81, we estimate that 387,347 clinicians will submit improvement activities as individuals during the 2019 MIPS performance period, 5,575 groups will submit improvement activities on behalf

of clinicians, and an additional 16 virtual groups will submit improvement activities, resulting in 392,938 total respondents.

The estimate of 387,347 individual clinicians is a distinct count by TIN/NPI of clinicians who submitted quality data under 2016 PQRS using an individual submission mechanism (claims, EHR, QCDR/Registry) and accounts for clinicians who submitted data using multiple submission mechanisms in order to increase the accuracy of our estimate of the number of individuals who will submit improvement activities. However, actual participation data for the 2017 MIPS performance period was unavailable in time for this proposed rule. Assuming actual participation data for the 2017 MIPS performance period is available in time to meet our final rule's publication schedule, we will use that data and revise our estimates in that rule.

Our burden estimates assume there will be no improvement activities burden for MIPS APM participants. We will assign the improvement activities performance category score at the APM level. We also assume that the MIPS APM models for the 2019 MIPS performance period will qualify for the maximum improvement activities performance category score and the APM Entities will not need to submit any additional improvement activities. Again, assuming actual participation data for the 2017 MIPS performance period is available in time to meet publication schedule for the final rule, we will use that data and revise our estimates in that rule. In Table 81, we estimate that approximately 392,938 respondents will be submitting data under the improvement activities performance category.

TABLE 81—ESTIMATED NUMBERS OF ORGANIZATIONS SUBMITTING IMPROVEMENT ACTIVITIES PERFORMANCE CATEGORY DATA ON BEHALF OF CLINICIANS

	Count
Number of clinicians to participate in improvement activities data submission as individuals during the 2019 MIPS performance period (a)	387,347
Number of Groups to submit improvement activities on behalf of clinicians during the 2019 MIPS performance period (b)	5,575
Number of Virtual Groups to submit improvement activities on behalf of clinicians during the 2019 MIPS performance period (c)	16
Total Number of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (d) = (a) + (b) + (c)	392,938
Total Number of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2018 MIPS performance period (e)	439,786
Difference between 2019 MIPS performance period and 2018 MIPS performance period (f) = (d) – (e)	– 46,848

As described in section III.H.3.h.(4)(b) of this preamble, for purposes of the 2021 MIPS payment year, we are proposing to revise § 414.1360(a)(1) to more accurately reflect the data submission process for the improvement activities performance category. In particular, instead of “via qualified registries; EHR submission mechanisms; QCDR, CMS Web Interface; or attestation,” as currently stated, we are revising the first sentence to state that data would be submitted “via direct, log in and upload, and log in and attest.” The revision would more closely align with the actual submission experience users have. We propose to decrease our burden estimates since the actual submission experience of the user is such that improvement activities data is submitted as part of the process for submitting quality and Promoting Interoperability data, resulting in less additional required time to submit improvement activities data.

The CY 2018 Quality Payment Program final rule, we estimated it would take 1 hour for a computer system analyst to submit data on the specified improvement activities (82 FR 53922). As a result of our proposal, we

estimate that the per response time required per individual or group is 5 minutes at \$89.18/hr for a computer system analyst to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials. Additionally, as stated in the CY 2018 Quality Payment Program final rule, the same improvement activity may be reported across multiple performance periods so many MIPS eligible clinicians will not have any additional information to submit for the 2019 MIPS performance period (82 FR 53921).

We are also proposing to add 6 new improvement activities for CY 2019 and future years, modify 5 existing improvement activities for CY 2019 and future years, and remove 1 existing improvement activity for CY 2019 and future years. Because MIPS eligible clinicians are still required to submit the same number of activities, we do not expect these proposals to affect our collection of information burden estimates. In addition, in order for an eligible clinician or group to receive credit for being a patient-centered medical home or comparable specialty

practice, the eligible clinician or group must attest in the same manner as any other improvement activity.

As shown in Table 82, we estimate an annual burden of 32,745 hours (392,938 responses × 5 minutes/60) at a cost of \$2,920,199 (32,745 hr × \$89.18/hr). Differences from the CY 2018 Quality Payment Program rule are based on updated QP data from the 2017 MIPS performance period, specifically the APM Participation List for the third snapshot date of the 2017 QP performance period.

Independent of the change to our per response time estimate, the decrease in the number of respondents results in an adjustment of – 46,848 hours at – \$4,177,904 (– 46,848 respondents × 1 hr × \$89.18/hr). Accounting for the change in number of respondents, the decrease in the time to submit improvement activities data results in an adjustment of – 360,193 hours at – \$32,122,027 (392,938 respondents × 55 minutes/60 × \$89.18/hr). When these adjustments are combined, the total adjustment is – 407,041 hours (– 46,848 – 360,193) hours at – \$36,299,931 (– \$4,177,904 – \$32,122,027).

TABLE 82—ESTIMATED BURDEN FOR IMPROVEMENT ACTIVITIES SUBMISSION

	Burden estimate
Total Number of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (a)	392,938
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c)	32,745
Labor rate for a computer systems analyst to submit improvement activities (d)	\$89.18/hr
Total Annual Cost (e) = (a) * (d)	\$2,920,184

13. Quality Payment Program ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

The proposed requirements and burden discussed under this section

will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule for

our previous burden estimates for nomination of improvement activities under the Quality Payment Program (82 FR 53922). In this CY 2019 Quality Payment Program rule, we are proposing

to adjust the number of respondents based on more recent data and adjust our per response time estimate based on our review of our currently approved burden estimates against the existing process for nomination of improvement activities. We are also proposing to adopt one new criteria and remove one existing criteria for nominating new improvement activities beginning with the CY 2019 performance period and future years. Furthermore, we are making clarifications to: (1) Considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities. We believe these proposals will not affect our currently approved burden estimates since they do not substantively impact the level of effort previously estimated to nominate an Improvement Activity.

We are also proposing to change the performance year for which the nominations would apply, such that improvement activities nominations received in a particular year will be vetted and considered for the next year's rulemaking cycle for possible implementation in the following year. Additionally, we are modifying the Improvement Activity submission form by adding a data field to allow submitters to clearly denote submission of a modification. This is to clarify the process for submitting modifications of existing Improvement Activities as discussed in the CY 2018 Quality Payment Program final rule (82 FR 53656). Finally, we are proposing to

change the submission timeframe for the Call for Activities from February 1st through March 1st to February 1st through June 30th providing approximately four additional months for stakeholders to submit nominations. We believe these proposals will not affect our our currently approved burden estimates since we believe that the number of nominations is unlikely to change, but the quality of the nominations is likely to increase given the additional time provided.

For the 2018 MIPS performance period, we provided opportunity for stakeholders to propose new activities formally via the Annual Call for Activities nomination form that was posted on the CMS website (82 FR 53657). The 2018 Annual Call for Activities lasted from March 2, 2017 through March 1, 2018 for which we received 72 nominations consisting of a total of 125 activities which were evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2019 Improvement Activities Inventory. Based on the number of activities being evaluated during the 2018 Annual Call for Activities (125 activities), we estimate that the total number of nominations we will receive for the 2019 Annual Call for Activities would continue to be 125, unchanged from the number of activities evaluated in CY 2018, which is a decrease from the 150 nominations currently approved by OMB.

In the CY 2018 Quality Payment Program final rule, we estimated that it

takes 0.5 hours to nominate an improvement activity (82 FR 53922). As shown in Table 83, due to a review of the nomination process including the criteria required to nominate an improvement activity, we now estimate it would take 2 hours (per organization) to submit an activity to us. Of those hours, we estimate it would take 1.2 hours at \$107.38/hr for a practice administrator or equivalent to make a strategic decision to nominate and submit that activity and 0.8 hours at \$206.44/hr for a clinician's review. In aggregate we estimate an annual burden of 250 hours (125 nominations \times 2 hr/nomination) at a cost of \$36,751 (125 \times [(1.2 hr \times \$107.38/hr) + (0.8 hr \times \$206.44/hr)]).

The percentage of practice administrator and clinician labor in relation to the total is unchanged from the CY 2018 Quality Payment Program final rule (82 FR 53922).

Independent of the change to our per response time estimate, the decrease in the number of nominations results in an adjustment of -12.5 hours and -\$1,837 (-25 activities \times [(0.3 hr \times \$107.38/hr) + (0.2 hr \times \$206.44/hr)]). Accounting for the decrease in the number of nominated improvement activities, the increase in time per nominated improvement activity results in an adjustment of 187.5 hours and \$27,563 (125 activities \times [(0.9 hr \times \$107.38/hr) + (0.6 hr \times \$206.44/hr)]). When these adjustments are combined, the total adjustment is 175 hours (187.5 - 12.5) and \$25,726 (\$27,563 - \$1,837).

TABLE 83—ESTIMATED BURDEN FOR NOMINATION OF IMPROVEMENT ACTIVITIES

	Burden estimate
Number of Organizations Nominating New Improvement Activities (a)	125
Number of Hours Per Practice Administrator to Identify and Propose Activity (b)	1.2
Number of Hours Per Clinician to Identify Activity (c)	0.8
Annual Hours Per Respondent (d) = (b) + (c)	2
Total Annual Hours (e) = (a) * (d)	250
Cost to Identify and Submit Activity (@ practice administrator's labor rate of \$107.38/hr.) (f)	\$128.86
Cost to Identify Improvement Activity (@ physician's labor rate of \$206.44/hr.) (g)	\$165.15
Total Annual Cost Per Respondent (h) = (f) + (g)	\$294.01
Total Annual Cost (i) = (a) * (h)	\$36,751

14. Quality Payment Program ICRs Regarding CMS Study on Factors Associated With Reporting Quality Measures

During each performance year, eligible clinicians are recruited to participate in the CMS study on the burden associated with reporting quality measures. Eligible clinicians who are

interested in participating can sign up whereby an adequate sample size is then selected by CMS from this group of potential participants. This study is ongoing, and participants are recruited on a yearly basis. Current participants can sign up when the study year ends.

Section 1848(s)(7) of the Act, as added by section 102 of the MACRA (Pub. L. 114–10) states that Chapter 35 of title

44, United States Code, shall not apply to the collection of information for the development of quality measures. Consequently, we are not setting out such burden since the study shall inform us (and our contractors) on the root causes of clinicians' performance measure data collection and data submission burdens and challenges that hinders accurate and timely quality

measurement activities. We refer readers to the discussion of this policy in the regulatory impact analysis section (section VII.F.7) of this proposed rule.

15. Quality Payment Program ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, this rule's proposed provisions would not necessitate the need to add or revise or delete any claims data fields. Therefore, we do not anticipate any new or additional submission requirements and/or burden for MIPS eligible clinicians.

16. Quality Payment Program ICRs Regarding Partial QP Elections (§ 414.1430)

This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to QP elections. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

APM Entities may face a data submission burden under MIPS related to Partial QP elections. Advanced APM participants will be notified about their QP or Partial QP status as soon as possible after each QP determination. Where Partial QP status is earned at the APM Entity level the burden of Partial QP election would be incurred by a representative of the participating APM Entity. Where Partial QP status is earned at the eligible clinician level, the burden

of Partial QP election would be incurred by the eligible clinician. For the purposes of this burden estimate, we assume that all MIPS eligible clinicians determined to be Partial QPs will participate in MIPS.

Based on our predictive QP analysis for the 2019 QP performance period, we estimate that 6 APM Entities and 75 eligible clinicians will make the election to participate as a Partial QP in MIPS (see Table 84), an increase of 64 from the 17 elections currently approved by OMB under the aforementioned control number. We estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate we estimate an annual burden of 20.25 hours (81 respondents \times .25 hr/election) at a cost of \$1,805.90 (20.25 hours \times \$89.18/hr). The increase in the number of Partial QP elections results in an adjustment of 16 hours and \$1,431 (64 elections \times 0.25 hrs \times \$89.18/hr).

TABLE 84—ESTIMATED BURDEN FOR PARTIAL QP ELECTION

	Burden estimate
Number of respondents making Partial QP election (6 APM Entities, 75 eligible clinicians) (a)	81
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25 hours
Total Annual Hours (c) = (a) * (b)	20.25 hours
Labor rate for computer systems analyst (d)	\$89.18/hr
Total Annual Cost (d) = (c) * (d)	\$1,805.90

17. Quality Payment Program ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1440) and Eligible Clinician Initiated Process (§ 414.1445)

As indicated below, the proposed requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Payer Initiated Process (§ 414.1440): This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the Payer Initiated Process. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option will be an available pathway to QP status for eligible clinicians participating sufficiently in Advanced APMs and Other Payer Advanced APMs. The All-Payer Combination Option allows for eligible clinicians to achieve QP status through

their participation in both Advanced APMs and Other Payer Advanced APMs. In order to include an eligible clinician's participation in Other Payer Advanced APMs in their QP threshold score, we will need to determine if certain payment arrangements with other payers meet the criteria to be Other Payer Advanced APMs. To provide eligible clinicians with advance notice prior to the start of a given performance period, and to allow other payers to be involved prospectively in the process, the 2018 CY Quality Payment Program final rule established a payer-initiated process for identifying payment arrangements that qualify as Other Payer Advanced APMs (82 FR 53844). The payer-initiated process for Other Payer Advanced APM determinations began in CY 2018 for Medicaid, Medicare Health Plans, and payers participating in CMS multi-payer models. Payers seeking to submit payment arrangement information for Other Payer Advanced APM determination through the payer-initiated process are required to complete a Payer Initiated Submission Form, instructions for which can be

found at <https://qpp.cms.gov/Determinations> made in 2018 are applicable for the Quality Payment Program Year 3. Also in that rule the remaining other payers, including commercial and other private payers, may request that we determine whether other payer arrangements are Other Payer Advanced APMs starting prior to the 2020 QP performance period and each performance period thereafter (82 FR 53867).

As shown in Table 85, we estimate that in 2019 for the 2020 QP performance period 165 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (15 Medicaid payers, 100 Medicare Advantage Organizations, and 50 Multi-payers), a decrease of 135 from the 300 total requests currently approved by OMB under the aforementioned control number. We estimate it would take 10 hours at \$89.18/hr for a computer system analyst per arrangement submission. In aggregate we estimate an annual burden of 1,650 hours (165 submissions \times 10 hr/submission) at a cost of \$147,147 (1,650 hr \times \$89.18/hr). The decrease in the number of payer-

initiated requests results in an adjustment of – 1,350 hours and – \$120,393 (– 135 requests × 10 hr × \$89.18/hr).

TABLE 85—ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM IDENTIFICATION DETERMINATIONS: PAYER-INITIATED PROCESS

	Burden estimate
Number of other payer payment arrangements (15 Medicaid, 100 Medicare Advantage Organizations, 50 Multi-payers) (a)	165
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	1,650
Labor rate for a computer systems analyst (d)	\$89.18/hr
Total Annual Cost for Other Payer Advanced APM determinations (e) = (a) * (d)	\$147,147

Eligible Clinician Initiated Process (§ 414.1445): This rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the Eligible Clinician Initiated Process. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option will be an available pathway to QP status for eligible clinicians participating sufficiently in Advanced APMs and Other Payer Advanced APMs. The All-Payer Combination Option allows for eligible clinicians to achieve QP status through their participation in both Advanced APMs and Other Payer Advanced APMs. In order to include an eligible clinician's participation in Other Payer Advanced APMs in their QP threshold score, we will need to determine if certain payment arrangements with other payers meet the criteria to be Other Payer Advanced APMs.

To provide eligible clinicians with advance notice prior to the start of a given performance period, and to allow other payers to be involved prospectively in the process, the CY 2018 Quality Payment Program final rule provided a payer-initiated identification process for identifying payment arrangements that qualify as

Other Payer Advanced APMs (82 FR 53854). In the same rule, under the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements would have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs (82 FR 53857–53858). However, to appropriately implement the statutory requirement to exclude from the All Payer Combination Option QP threshold calculations certain Title XIX payments and patients, we determined it would be problematic to allow APM Entities and eligible clinicians to request determinations for Title XIX payment arrangements after the conclusion of the QP performance period because any late-identified Medicaid APM or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria could unexpectedly affect QP threshold calculations for every other clinician in that state (or county). Thus, the CY 2018 Quality Payment Program final rule provided that APM Entities and eligible clinicians may request determinations for any Medicaid payment arrangements in which they are participating at an earlier point, prior to the start of a given QP performance period (82 FR 53858). This would allow all clinicians in a given state or county to know before the beginning of the performance period whether their Title XIX payments and

patients would be excluded from the all-payer calculations that are used for QP determinations for the year under the All-Payer Combination Option. This Medicaid specific eligible clinician-initiated determination process for Other Payer Advanced APMs also began in CY 2018, and determinations made in 2018 are applicable for the Quality Payment Program Year 3. Eligible clinicians or APM Entities seeking submit payment arrangement information for Other Payer Advanced APM determination through the Eligible Clinician-Initiated process are required to complete an Eligible Clinician Initiated Submission Form, instructions for which can be found at <https://qpp.cms.gov/>.

As shown in Table 86, we estimate that 150 other payer arrangements will be submitted by APM Entities and eligible Other Payer Advanced APM determinations, an increase of 75 from the 75 total requests currently approved by OMB under the aforementioned control number.

We estimate it would take 10 hours at \$89.18/hr for a computer system analyst per arrangement submission. In aggregate we estimate an annual burden of 1,500 hours (150 submissions × 10 hr/submission) at a cost of \$133,770 (1,500 hr × \$89.18/hr). The increase in the number of clinician-initiated requests results in an adjustment of 750 hours and \$66,885 (75 requests × 10 hr × \$89.18/hr).

TABLE 86—ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM DETERMINATIONS: ELIGIBLE CLINICIAN INITIATED PROCESS

	Burden estimate
Number of other payer payment arrangements from APM Entities and eligible clinicians	150
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	1,500
Labor rate for a computer systems analyst (d)	\$89.18/hr

TABLE 86—ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM DETERMINATIONS: ELIGIBLE CLINICIAN INITIATED PROCESS—Continued

	Burden estimate
Estimated Total Annual Cost for Other Payer Advanced APM determinations (e) = (a) * (d)	\$133,770

Submission of Data for QP Determinations under the All-Payer Combination Option (§ 414.1440): The following reflects the burden associated with the first year of data collection resulting from policies set out in the CY 2018 Quality Payment Program final rule. Because no collection of data was required prior to the CY 2019 performance period, the requirements and burden were not submitted to OMB for approval. However, by virtue of this proposed rulemaking the requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

The CY 2017 Quality Payment Program final rule, provided that either APM Entities or individual eligible clinicians must submit by a date and in a manner determined by us: (1) Payment arrangement information necessary to assess whether each other payer arrangement is an Other Payer Advanced APM, including information on financial risk arrangements, use of CEHRT, and payment tied to quality measures; (2) for each payment arrangement, the amounts of payments for services furnished through the arrangement, the total payments from the payer, the numbers of patients furnished any service through the arrangement (that is, patients for whom the eligible clinician is at risk if actual expenditures exceed expected expenditures), and (3) the total number of patients furnished any service through the arrangement (81 FR 77480). The rule also specified that if we do not receive sufficient information to complete our evaluation of another payer arrangement and to make QP determinations for an eligible clinician using the All-Payer Combination Option, we would not assess the eligible clinicians under the All-Payer Combination Option (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we explained that in order for us to make QP determinations under the All-Payer Combination Option using either the payment

amount or patient count method, we would need to receive all of the payment amount and patient count information: (1) Attributable to the eligible clinician or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician during the QP performance period (82 FR 53885). We also finalized that eligible clinicians and APM Entities will not need to submit Medicare payment or patient information for QP determinations under the All-Payer Combination Option (82 FR 53885).

The CY 2018 Quality Payment Program final rule noted that we will need this payment amount and patient count information for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31 (82 FR 53885). We noted that the timing may be challenging for APM Entities or eligible clinicians to submit information for the August 31 snapshot date. If we receive information for either the March 31 or June 30 snapshots, but not the August 31 snapshot, we will use that information to make QP determinations under the All-Payer Combination Option. This payment amount and patient count information is to be submitted in a way that allows us to distinguish information from January 1 through March 31, January 1 through June 30, and January 1 through August 31 so that we can make QP determinations based on the two proposed snapshot dates (82 FR 30203 through 30204).

The CY 2018 Quality Payment Program final rule specified that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the

calendar year that is 2 years prior to the payment year, which we refer to as the QP Determination Submission Deadline (82 FR 53886).

In section III.H.4.g.(4)(b) of this rule, we are proposing to add a third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights to the TIN participate in a single APM Entity. This option would therefore be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It would also be available to any other TIN for which all clinicians who have reassigned billing rights to the TIN are participating in a single APM Entity. To make QP determinations under the All-Payer Combination Option at the TIN level as proposed using either the payment amount or patient count method, we would need to receive, by December 1 of the calendar year that is 2 years prior to the payment year, all of the payment amount and patient count information: (1) Attributable to the eligible clinician, TIN, or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician(s) during the QP performance period for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31 sufficient for us to make QP determinations.

As shown in Table 87, we assume that 4 APM Entities, 8 TINs, and 80 eligible clinicians will submit data for QP determinations under the All-Payer Combination Option in 2019. We estimate it will take the APM Entity representative, TIN representative, or eligible clinician 5 hours at \$107.38/hr for a practice administrator to complete this submission. In aggregate, we estimate an annual burden of 460 hours (92 respondents × 5 hr) at a cost of \$49,395 (460 hr × \$107.38/hr).

TABLE 87—ESTIMATED BURDEN FOR THE SUBMISSION OF DATA FOR ALL-PAYER QP DETERMINATIONS

	Burden estimate
Number of APM Entities submitting data for All-Payer QP Determinations (a)	4

TABLE 87—ESTIMATED BURDEN FOR THE SUBMISSION OF DATA FOR ALL-PAYER QP DETERMINATIONS—Continued

	Burden estimate
Number of TINs submitting data for All-Payer QP Determinations (b)	8
Number of eligible submitting data for All-Payer QP Determinations (c)	80
Hours Per respondent QP Determinations (d)	5
Total Hours (g) = [(a) * (d)] + [(b) * (d)] + [(c) * (d)]	460
Labor rate for a Practice Administrator (\$107.38) (h)	\$107.38/hr
Total Annual Cost for Submission of Data for All-Payer QP Determinations (i) = (g) * (h)	\$49,395

18. Quality Payment Program ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Physician Compare (§ 414.1395)

The proposed requirements and burden associated with this data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We estimate that 10 percent of the total clinicians and groups who will voluntarily participate in MIPS will also elect not to participate in public reporting. This results in a total of 10,433 (10 percent × 104,326 voluntary MIPS participants), a decrease of 11,967

from the total respondents currently approved by OMB under the aforementioned control number due to the reduction in voluntary participation in MIPS overall. As we discussed earlier in this section, voluntary respondents are the clinicians that submitted data to PQRS, are not QPs, and are expected to be excluded from MIPS after applying the eligibility requirements discussed in section III.H.3.a. of this rule. In implementing the proposed opt-in policy, we estimated that 33 percent of clinicians that exceed 1 of the low-volume criteria, but not all 3, would elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a

voluntary reporter. This logic was also applied in the regulatory impact analysis of this rule. Table 88 shows that for these voluntary participants, we estimate it would take 0.25 hours at \$89.18/hr for a computer system analyst to submit a request to opt-out. In aggregate we estimate an annual burden of 2,608.25 hours (10,433 requests × 0.25 hr/request) at a cost of \$232,604 (2,608.25 hr × \$89.18/hr).

The decrease in the number of respondents due to policies proposed in this rule results in a decrease of – 2,991.75 hours (– 11,967 respondents × 0.25 hr) and – \$266,804 (– 2,991.75 hours × \$89.18/hr).

TABLE 88—ESTIMATED BURDEN FOR VOLUNTARY PARTICIPANTS TO ELECT OPT OUT OF PERFORMANCE DATA DISPLAY ON PHYSICIAN COMPARE

	Burden estimate
Number of Voluntary Participants Opting Out of Physician Compare (a)	10,433
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours for Opt-out Requester (c) = (a) * (b)	2,608.25
Labor rate for a computer systems analyst (d)	\$89.18/hr
Total Annual Cost for Opt-out Requests (e) = (a) * (d)	\$232,604

19. Summary of Annual Quality Payment Program Burden Estimates

Table 89 summarizes this proposed rule's burden estimates for the Quality Payment Program. In order to understand the burden implications of

the policies proposed in this rule, we have also estimated a baseline burden of continuing the policies and information collections set forth in the CY 2018 Quality Payment Program final rule into the 2019 MIPS performance period. Our baseline burden estimates reflect the

recent availability of data sources to more accurately reflect the number of the organizations exempt from the Promoting Interoperability performance category and to more accurately reflect the exclusion of QPs from all MIPS performance categories.

TABLE 89—SUMMARY OF PROPOSED QUALITY PAYMENT PROGRAM BURDEN ESTIMATES AND REQUIREMENTS

Requirement	Currently approved respondents	Proposed respondents	Change in respondents	Currently approved total burden hours	Proposed total burden hours	Change in total burden hours
ICRs Under OMB Control Number 0938–1314 (CMS–10621)						
§ 414.1400 Registry self-nomination *	120	150	30	1,200	450	– 750
§ 414.1400 QCDR self-nomination *	113	200	87	1,130	2,400	1,270
§ 414.1325 and 414.1335 CMS Enterprise Portal User Account Registration	0	3,741	3,741	0	3,741	3,741
§ 414.1325 and 414.1335 (Quality Performance Category) Claims Collection Type	278,039	274,702	– 3,337	4,949,094	3,900,768	– 1,048,326
§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type	107,217	107,056	– 161	973,852	972,390	– 1,462

TABLE 89—SUMMARY OF PROPOSED QUALITY PAYMENT PROGRAM BURDEN ESTIMATES AND REQUIREMENTS—Continued

Requirement	Currently approved respondents	Proposed respondents	Change in respondents	Currently approved total burden hours	Proposed total burden hours	Change in total burden hours
§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type	54,218	53,529	– 689	487,962	428,232	– 59,730
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface Submission Type	296	286	– 10	21,904	16,931.2	– 4,972.8
§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface	10	67	57	10	16.75	6.75
(Quality Performance Category) Call for Quality Measures	40	140	100	20	630	610
§ 414.1375 (Promoting Interoperability Performance Category) Application for Promoting Interoperability Reweighting	40,645	87,211	46,566	20,323	21,803	1,480
§ 414.1375 (Promoting Interoperability Performance Category) Data Submission	218,215	67,622	– 150,593	654,645	180,325	– 474,320
(Promoting Interoperability Performance Category) Call for Promoting Interoperability Measures	40	47	7	20	23.5	3.5
§ 414.1360 (Improvement Activities Performance Category) Data Submission	439,786	392,938	– 46,848	439,786	32,744.8	– 407,041.2
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities	150	125	– 25	75	250	– 175
§ 414.1430 Partial Qualifying APM Participant (QP) Election	17	81	64	4.25	20.25	16
§ 414.1440 Other Payer Advanced APM Identification: Payer Initiated Process	300	165	– 135	3,000	1,650	– 1,350
§ 414.1445 Other Payer Advanced APM Identification: Eligible Clinician Initiated Process	75	150	75	750	1,500	750
§ 414.1440 Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	0	92	92	0	460	460
§ 414.1395 (Physician Compare) Opt Out for Voluntary Participants ..	22,400	10,433	– 11,967	5,600	2,608.25	– 2,991.75
<i>Subtotal</i>	<i>1,161,681</i>	<i>998,735</i>	<i>– 162,946</i>	<i>7,559,375</i>	<i>5,566,944</i>	<i>– 1,992,782</i>
ICRs Under OMB Control Number 0938–1222 (CMS–10450)						
§ 414.1325 and 414.1335 (CAHPS for MIPS Survey) Beneficiary Participation	132,307	65,793	– 66,514	29,108	14,145	– 14,963
§ 414.1325 and 414.1335 (CAHPS for MIPS Survey) Group Registration	461	454	– 7	691.5	340.5	– 351
<i>Subtotal</i>	<i>132,768</i>	<i>66,247</i>	<i>– 66,521</i>	<i>29,800</i>	<i>14,485.5</i>	<i>– 15,314</i>
Total	1,294,449	1,064,982	– 229,467	7,589,175	5,581,429	– 2,008,096

* These two ICRs were combined in a single ICR in the CY 2018 Quality Payment Program final rule (82 FR 53906 through 53907).

Table 90 provides the reasons for changes in the estimated burden for information collections in this proposed rule. We have divided the reasons for

our change in burden into those related to new policies and those related to changes in the baseline burden of continued Quality Payment Program

Year 2 policies that reflect updated data and methods.

TABLE 90—REASONS FOR CHANGE IN BURDEN COMPARED TO THE CURRENTLY APPROVED CY 2018 INFORMATION COLLECTION BURDENS

Table in collection of information	Changes in burden due to finalized Year 3 policies	Changes to “baseline” of burden continued Year 2 policy (<i>italics are changes in number of respondents due to updated data</i>)
Table 63: Qualified Registry Self-Nomination.	None	After a review of the self-nomination process, we determined it is more accurate to separately assess the burden of Qualified Registry and QCDR self-nomination rather than aggregate them in the same ICR. Review of self-nomination process resulted in a decrease in estimated time needed to complete simplified self-nomination (– 9.5 hr. computer system analyst time) and full self-nomination (– 7 hr. computer system analyst time). <i>Increase in the number of respondents as the number of qualified registries enrolling increases and the basis for estimating the number of respondents is updated to reflect the number of self-nomination applications received in place of the number of qualified registries being approved.</i>
Table 64: QCDR Self-Nomination	None	After a review of the self-nomination process, we determined it is more accurate to separately assess the burden of Qualified Registry and QCDR self-nomination rather than aggregate them in the same ICR. Review of self-nomination process resulted in an increase in estimated time needed to complete simplified self-nomination (– 0.5 hr. computer system analyst time) and full self-nomination (+2 hr. computer system analyst time). <i>Increase in the number of respondents as the number of QCDRs enrolling increases and the basis for estimating the number of respondents is updated to reflect the number of self-nomination applications received in place of the number of QCDRs being approved.</i>

TABLE 90—REASONS FOR CHANGE IN BURDEN COMPARED TO THE CURRENTLY APPROVED CY 2018 INFORMATION COLLECTION BURDENS—Continued

Table in collection of information	Changes in burden due to finalized Year 3 policies	Changes to "baseline" of burden continued Year 2 policy (<i>italics are changes in number of respondents due to updated data</i>)
Table 68: Quality Payment Program Identity Management Application Process.	None	<i>Decreased number of respondents due to updates to the identity management system being used for data submission; only new respondents submitting quality data using the CMS Enterprise Portal need to create a new account, versus system where all respondents submitting via EHR needed to register for user account annually.</i>
Table 69: Quality Performance Category Claims Collection Type.	None	<i>Decreased number of respondents due to increase in the number of QPs excluded from submitting data.</i> <i>Correction to estimate to account for reduced number of required measures compared to PQRS (6 in MIPS; 9 in PQRS) reduced estimated time to submit data.</i>
Table 70: Quality Performance Category QCDR/MIPS CQM Collection Type.	None	<i>Decreased number of respondents due to increase in the number of QPs excluded from submitting data.</i>
Table 71: Quality Performance Category eCQM Collection Type.	None	<i>Decreased number of respondents due to increase in the number of QPs excluded from submitting data.</i>
Table 72: Quality Performance Category CMS Web Interface.	Decrease in number of required measures resulted in reduction in estimated time needed to submit data (–14.8 hrs computer system analyst time).	<i>Decrease in the number of respondents as fewer eligible group practices elected to submit data using the CMS Web Interface.</i>
Table 73: Beneficiary Responses to CAHPS for MIPS Survey.	None	<i>Decrease in the number of respondents as fewer eligible group practices elect to have vendors administer the CAHPS for MIPS survey and fewer beneficiaries per group respond to the survey, on average.</i>
Table 74: Registration for CMS Web Interface.	None	<i>Increase in the number of respondents as more groups register to submit data using the CMS Web Interface.</i> <i>Review of registration process resulted in decrease in estimated time to register. (–0.75 hr. computer system analyst time).</i>
Table 75: Registration for CAHPS for MIPS Survey.	None	<i>Decrease in the number of respondents as fewer eligible group practices elect to have vendors administer the CAHPS for MIPS survey.</i> <i>Review of registration process resulted in decrease in estimated time to register. (–0.75 hr. computer system analyst time).</i>
Table 76: Call for Quality Measures	None	<i>Increase in the number of new quality measures being nominated.</i> <i>Inclusion of time required to complete Peer Review Journal Article Form resulted in increase in time to nominate a quality measure. This was a requirement in the CY 2017 Quality Payment Program final rule (81 FR 77153 through 77155), but was not included in burden estimates. (+4 hrs Physician time).</i>
Table 77: Application for Promoting Interoperability Reweighting.	None	<i>Increase in the number of respondents as the estimated number of APM Entities with hardship approval was previously not included.</i> <i>Review of application process resulted in decrease in estimated time to apply (–0.25 hr computer system analyst time).</i>
Table 79: Promoting Interoperability Performance Category Data Submission.	Decrease in number of required measures resulted in reduction in estimated time needed to submit data (–.33 hr computer system analyst time).	<i>Decrease in the number of respondents due to increase in the estimate of hospital-based clinicians and clinicians in small practices, more accurate estimate of the number of TINs submitting data for MIPS APMs, and accounting for individuals which may have submitted quality data via two or more submission or collection types.</i>
Table 80: Call for Promoting Interoperability Measures.	None	<i>Increase in the number of new Promoting Interoperability measures being nominated.</i>
Table 82: Improvement Activities Submission.	None	<i>Decreased number of respondents due to increase in the number of QPs excluded from submitting data and accounting for individuals which may have submitted quality data via two or more submission or collection types.</i> <i>Review of submission process resulted in decrease in estimated time to submit (–0.92 hr computer system analyst time).</i>
Table 83: Nomination of Improvement Activities.	None	<i>Review of nomination process resulted in increase in estimated time to nominate a new improvement activity (+0.9 hrs Practice Administrator time; +0.6 hrs Physician time).</i>
Table 84: Partial QP Election	None.	
Table 85: Other Payer Advanced APM Identification: Other Payer Initiated Process.	None	<i>Decrease in the number of anticipated other payer arrangements submitted for identification as Other Payer Advanced APMs.</i>
Table 86: Other Payer Advanced APM Identification: Eligible Clinician Initiated Process.	None	<i>Increase in the number of anticipated other payer arrangements submitted by APM Entities and eligible clinicians for identification as Other Payer Advanced APMs.</i>
Table 87: Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option.	Reflects new policy in this proposed rule.	None.
Table 88: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare.	<i>Decrease in the number of respondents as a result of fewer individuals and groups being excluded from MIPS eligibility.</i>	None.

C. Summary of Annual Burden
Estimates for Proposed Requirements

TABLE 91—ANNUAL REQUIREMENTS AND BURDEN

Regulation section(s) under Title 42 of the CFR	OMB control No.***	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting (\$/hr)	Total cost (\$)*
414.94(j) (AUC consultations)	0938–1345	586,386	43,181,818	0.033 (2 min) ...	1,425,000	varies	119,275,350
Quality Payment Program (See Subtotal Under Table 89).	0938–1314	(**)	(162,946)	varies	(1,992,782)	varies	(177,891,746)
Quality Payment Program (See Subtotal Under Table 89).	0938–1222	(66,521)	(66,521)	varies	(15,314)	varies	(394,855)
Total		1,187,338	42,952,351	varies	(583,096)	varies	(59,011,251)

*With respect to the PRA, this rule would not impose any non-labor costs.

**We are unable to accurately calculate a total number of respondents for the Quality Payment Program. In many cases, individuals, groups, and entities have responded to multiple data collections and there is no unified way to identify unique respondents.

***OMB and CMS' PRA package ID numbers: OMB 0938–1345 (CMS–10654), OMB 0938–1314 (CMS–10621), and OMB 0938–1222 (CMS–10450). 0938–1222 (CMS–10450).

D. Submission of PRA-Related Comments

We have submitted a copy of this rule's information collection and recordkeeping requirements to OMB for review and approval. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS's website at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please refer to the **DATES** and **ADDRESSES** sections of this rulemaking for instructions. We will consider all ICR-related comments received by the date and time specified in the **DATES** section, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

This proposed rule makes payment and policy changes under the Medicare PFS and implements required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Achieving a Better Life Experience Act (ABLE), the Protecting Access to Medicare Act of 2014

(PAMA), section 603 of the Bipartisan Budget Act of 2015, the Consolidated Appropriations Act of 2016, and the Bipartisan Budget Act of 2018. This proposed rule also makes changes to payment policy and other related policies for Medicare Part B, Part D, and Medicare Advantage.

In addition, section 218(b) of the PAMA added section 1834(q) of the Act directing the Secretary to establish a program to promote the use of AUC. Section 1834(q)(4) of the Act requires ordering professionals to consult with specified applicable AUC through a qualified CDSM for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system, and for the furnishing professional or facility to include on the Medicare claim information about the ordering professional's consultation with specified applicable AUC through a qualified CDSM. This proposed rule is necessary to make policy changes under Medicare fee-for-service. Therefore, we include a detailed regulatory impact analysis to assess all costs and benefits of available regulatory alternatives and explained the selection of these regulatory approaches that we believe adhere to section 1834(q) of the Act and, to the extent feasible, maximize net benefits.

This proposed rule also makes payment and policy changes under the Medicare Physician Fee Schedule and makes required statutory changes under the MACRA, as amended by section 51003 of the Bipartisan Budget Act of 2018.

Proposed new policies for CY 2019 are detailed throughout this proposed rule. For example, the proposals associated with modernizing Medicare physician payment by recognizing communication technology-based services are described in section II.D. of this proposed rule, while the proposals associated with E/M visits are described in section II.I. of this proposed rule. Several proposals using innovative

technology that enables remote services would expand access to care and create more opportunities for patients to access more personalized care management as well as connect with their physicians more quickly. These proposals would support access to care using telecommunications technology by: Paying clinicians for virtual check-ins—brief, non-face-to-face appointments via communications technology; paying clinicians for evaluation of patient-submitted photos; and expanding Medicare-covered telehealth services to include prolonged preventive services.

Several provisions in the proposed rule would also help to free electronic health records to be powerful tools to support efficient care while giving physicians more time to spend with their patients, especially those with complex needs, rather than on paperwork. Specifically, the E/M proposal would: Simplify, streamline, and offer flexibility in documentation and coding requirements for E/M visits, which make up about 40 percent of allowed charges under the PFS and consume much of clinicians' time; reduce unnecessary physician supervision of radiologist assistants during diagnostic services; and remove burdensome and overly complex functional reporting requirements for outpatient therapy. In addition, Section VII.H. of this Regulatory Impact Analysis details the economic effect of these proposed policies on Medicare providers and beneficiaries.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March

22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate, as discussed in this section, that the PFS provisions included in this proposed rule would redistribute more than \$100 million in 1 year. Therefore, we estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details see the SBA’s website at <http://www.sba.gov/content/table-small-business-size-standards> (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards.

There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this proposed rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

For example, the effects of changes to payment rates for practitioners, other providers, and suppliers are discussed in VII.C. of this proposed rule. Alternative options considered to the proposed payment rates are discussed generally in section VII.F of this proposed rule, while specific alternatives for individual codes are discussed throughout this rule, especially in section II.H.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The PFS does not reimburse for services provided by rural hospitals; the PFS pays for physicians’ services, which can be furnished by physicians and non-physician practitioners in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$150 million. This proposed rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on

state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This proposed rule is considered an E.O. 13771 regulatory action because it is expected to result in regulatory costs. The estimated impact would be \$5 million in costs in 2019, \$4.114 billion in costs in 2020, and \$44 million in cost savings in 2021 and thereafter. Annualizing these costs and cost savings in perpetuity and discounting at 7 percent back to 2016, we estimate that this rule would generate \$174 million in annualized net costs for E.O. 13771 accounting purposes. Details on the estimated costs of this rule can be found in the following analyses.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we are implementing a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than \$20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compare payment rates for CY 2018 with payment rates for CY 2019 using CY 2017 Medicare utilization. The payment

impacts in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues would be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical

laboratory services that are paid under the Clinical Laboratory Fee Schedule.

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101(a) of the MACRA repealed the previous statutory update formula and amended section 1848(d) of the Act to specify the update adjustment factors for calendar years 2015 and beyond. The update adjustment factor for CY 2019, as required by section 53106 of the Bipartisan Budget Act of 2018, is 0.25 percent before applying other adjustments.

To calculate the proposed conversion factor for this year, we multiplied the product of the current year conversion factor and the update adjustment factor by the budget neutrality adjustment described in the preceding paragraphs. We estimate the CY 2019 PFS conversion factor to be 36.0463, which reflects the budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) and the 0.25 percent update adjustment factor specified under section 1848(d)(18) of the Act. We estimate the CY 2019 anesthesia conversion factor to be 22.2986, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 92—CALCULATION OF THE PROPOSED CY 2019 PFS CONVERSION FACTOR

CY 2018 Conversion Factor	35.9996
Statutory Update Factor	0.25 percent (1.0025)
CY 2019 RVU Budget Neutrality Adjustment	– 0.12 percent (0.9988)
CY 2019 Conversion Factor	36.0463

TABLE 93—CALCULATION OF THE PROPOSED CY 2019 ANESTHESIA CONVERSION FACTOR

CY 2018 National Average Anesthesia Conversion Factor	22.1887
Statutory Update Factor	0.25 percent (1.0025)
CY 2019 RVU Budget Neutrality Adjustment	– 0.12 percent (0.9988)
CY 2019 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.365 percent (1.00365)
CY 2019 Conversion Factor	22.2986

Table 94 shows the payment impact on PFS services of the proposals contained in this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in Table 94 (CY 2019 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 94.

- *Column A (Specialty)*: Identifies the specialty for which data are shown.
- *Column B (Allowed Charges)*: The aggregate estimated PFS allowed charges for the specialty based on CY 2017 utilization and CY 2018 rates. That is, allowed charges are the PFS amounts

for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.

- *Column C (Impact of Work RVU Changes)*: This column shows the estimated CY 2019 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes and the proposed changes to documentation and payment for the office/outpatient E/M code set. For additional information on this proposal see section II.I. of this proposed rule.

- *Column D (Impact of PE RVU Changes)*: This column shows the estimated CY 2019 impact on total allowed charges of the changes in the PE RVUs.

- *Column E (Impact of MP RVU Changes)*: This column shows the estimated CY 2019 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five-year review and update of MP RVUs.

- *Column F (Combined Impact)*: This column shows the estimated CY 2019 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 94—CY 2019 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact* (%)
(A)	(B)	(C)	(D)	(E)	(F)
TOTAL	\$92,173	0	0	0	0
ALLERGY/IMMUNOLOGY	238	1	–6	0	–5

TABLE 94—CY 2019 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY—Continued

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact* (%)
(A)	(B)	(C)	(D)	(E)	(F)
ANESTHESIOLOGY	1,889	0	0	0	0
AUDIOLOGIST	67	0	0	-1	-1
CARDIAC SURGERY	293	-1	-1	1	-1
CARDIOLOGY	6,590	0	-1	0	-1
CHIROPRACTOR	749	0	1	0	0
CLINICAL PSYCHOLOGIST	770	0	2	0	2
CLINICAL SOCIAL WORKER	725	0	2	0	2
COLON AND RECTAL SURGERY	165	0	1	0	1
CRITICAL CARE	340	-1	0	0	0
DERMATOLOGY	3,477	1	-2	0	-1
DIAGNOSTIC TESTING FACILITY	728	0	-4	0	-4
EMERGENCY MEDICINE	3,110	0	0	0	0
ENDOCRINOLOGY	480	0	-1	0	-1
FAMILY PRACTICE	6,176	0	1	0	1
GASTROENTEROLOGY	1,750	-1	1	0	1
GENERAL PRACTICE	423	0	1	0	1
GENERAL SURGERY	2,079	0	0	0	1
GERIATRICS	196	-2	1	0	-1
HAND SURGERY	213	2	1	0	2
HEMATOLOGY/ONCOLOGY	1,737	-1	-3	0	-4
INDEPENDENT LABORATORY	640	0	4	0	4
INFECTIOUS DISEASE	645	-1	1	0	0
INTERNAL MEDICINE	10,698	0	1	0	1
INTERVENTIONAL PAIN MGMT	863	2	1	0	3
INTERVENTIONAL RADIOLOGY	384	1	-1	0	0
MULTISPECIALTY CLINIC/OTHER PHYS	148	-1	0	0	-1
NEPHROLOGY	2,182	-1	0	0	-1
NEUROLOGY	1,521	-1	-1	0	-2
NEUROSURGERY	798	0	0	1	1
NUCLEAR MEDICINE	50	-1	-1	0	-1
NURSE ANES/ANES ASST	1,163	0	0	0	0
NURSE PRACTITIONER	4,043	1	2	0	2
OBSTETRICS/GYNECOLOGY	635	3	1	0	4
OPHTHALMOLOGY	5,437	0	-1	0	-1
OPTOMETRY	1,301	1	0	0	1
ORAL/MAXILLOFACIAL SURGERY	67	1	-2	0	-1
ORTHOPEDIC SURGERY	3,730	1	0	0	1
OTHER	31	0	5	0	4
OTOLARNGOLOGY	1,206	2	-3	0	-1
PATHOLOGY	1,158	0	-1	0	-1
PEDIATRICS	61	-1	0	0	-1
PHYSICAL MEDICINE	1,102	-1	0	0	-1
PHYSICAL/OCCUPATIONAL THERAPY	3,930	0	-1	0	-1
PHYSICIAN ASSISTANT	2,447	1	0	0	1
PLASTIC SURGERY	373	1	0	0	1
PODIATRY	1,958	-1	0	0	-2
PORTABLE X-RAY SUPPLIER	98	0	1	0	1
PSYCHIATRY	1,177	0	2	0	3
PULMONARY DISEASE	1,709	-2	0	0	-2
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	1,760	0	-2	0	-2
RADIOLOGY	4,891	0	0	0	0
RHEUMATOLOGY	540	-1	-3	0	-4
THORACIC SURGERY	356	-1	-1	1	-1
UROLOGY	1,733	2	1	0	3
VASCULAR SURGERY	1,144	0	-2	0	-1

* Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2019 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the proposed RVU changes are generally related to the changes to

RVUs for specific services resulting from the Misvalued Code Initiative, including proposed RVUs for new and revised codes. Because office/outpatient E/M codes comprise a large volume of services in the PFS, much of the

specialty level impacts are being driven by our proposal to establish a single payment rate for new patients and a single PFS rate for established patients for E/M visits levels 2–5 as well as other adjustments including: The E/M

Multiple Procedure Payment Adjustment, the HCPCS G-code add-ons to recognize additional relative resources for certain kinds of visits, HCPCS G-codes to describe podiatric E/M visits, the technical adjustment to the PE methodology, and the HCPCS G-code for 30 minutes of prolonged services. For specific information on these proposals, see II.I. of this proposed rule. The estimated impacts for some specialties, including obstetrics/gynecology, urology, independent labs, and clinical psychologists, reflect increases relative to other physician specialties. These increases can largely be attributed to proposed increases in value for particular services, the proposed updates to supply and equipment pricing, and the proposed valuation of the E/M office visit codes that had a positive impact on specialties reporting a higher proportion of level 2 and level 3 office visits.

The estimated impacts for several specialties, including allergy/immunology, diagnostic testing facilities, hematology/oncology, radiation therapy centers, and podiatry, reflect decreases in payments relative to payment to other physician specialties. Allergy/immunology experiences a decrease due to a reduction in PE RVUs based on updated supply pricing for certain codes frequently billed by this specialty. For the other specialties, these decreases can largely be attributed to proposed revaluation of individual procedures, proposed decreases in relative payment as a result of proposed updates to prices for medical supplies and equipment, and the continued implementation of previously finalized code-level reductions that are being phased-in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the Clinical Laboratory Fee Schedule. As a result, the estimated 1 percent reduction for CY 2019 is only applicable to approximately 17 percent of the Medicare payment to these entities.

Additionally, specialties such as podiatry and dermatology that would experience a decrease in payments are those that bill a large portion of E/M visits on the same day as procedures, and therefore would see a reduction based on the application of the E/M MPPR adjustments. Other specialties, such as rheumatology and hematology/oncology are estimated to experience a decrease in payments due to the E/M proposals because they may tend to bill greater proportion of level 4 and 5 E/M visits and the add-on codes for inherent

visit complexity may not fully mitigate a reduction in their payments. Specialties such as OB/GYN and urology would see an increase in payments from these proposals, due to a combination of single PFS rates for E/M visit levels and the add-on codes for inherent visit complexity. For a more thorough discussion of the specialty level impacts of these proposals, see section II.I. of this proposed rule.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table, including comments received in response to the proposed rates. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentages in the table are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

b. Impact

Column F of Table 94 displays the estimated CY 2019 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under “downloads” on the CY 2019 PFS proposed rule website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/>. We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/>.

D. Effect of Changes Related to Telehealth

As discussed in section II.D. of this proposed rule, we are proposing to add two new codes, HCPCS codes G0513 and G0514, to the list of Medicare telehealth services. Although we expect these changes to have the potential to

increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the proposed additions, we estimate there will only be a negligible impact on PFS expenditures from the proposed additions. For example, for services already on the list, they are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall. This proposal is responsive to longstanding stakeholder interest in expanding Medicare payment for telehealth services. The restrictions placed on Medicare telehealth by the statute limit the magnitude of utilization; however, CMS believes there is value in allowing physicians and patients the greatest flexibility when appropriate.

E. Effect of Changes to Payment to Provider-Based Departments (PBDs) of Hospitals Paid Under the PFS

As discussed in section II.G of this proposed rule, we are proposing a PFS Relativity Adjuster of 40 percent for CY 2019, meaning that nonexcepted items and services furnished by nonexcepted off-campus PBDs would be paid under the PFS at a rate that is 40 percent of the OPPS rate. In developing our proposal to maintain the PFS Relativity Adjuster at 40 percent, we updated our analysis to include a full year of claims data. We estimated site-specific PFS rates for the technical component of a service for the entire range of HCPCS codes furnished in nonexcepted off campus PBDs. Next we compared the average, weighted by claim line volume, of the site specific rate under the PFS compared to the average rate under the OPPS, also weighted by claim line volume. This calculation resulted in a relative rate of approximately 40 percent, supporting a proposal to maintain the PFS Relativity Adjuster at 40 percent. There will be no additional savings for CY 2019 relative to CY 2018 because our proposed PFS Relativity Adjuster of 40 percent maintains the current rate which was finalized for CY 2018.

F. Other Provisions of the Proposed Regulation

1. Part B Drugs: Application of an Add-On Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments

In section II.N. of this rule, we proposed that effective January 1, 2019, WAC based payments for Part B drugs made under section 1847A(c)(4) of the Act would utilize a 3 percent add-on in place of the 6 percent add-on that is

currently being used. If this proposal is finalized, we would also permit MACs to use an add-on percentage of up to 3 percent for WAC-based payments for new drugs.

We anticipate that the proposed reduction to the add-on payment made for a subset of Part B drugs will result in savings to the Medicare program by bringing payment amounts for newly approved drugs closer to acquisition costs. The proposed 3 percent add-on is consistent with MedPAC's analysis and recommendations as well as discounts observed by MedPAC in their June 2017 Report to the Congress. We have also considered how CMS's experience with WAC-based pricing for recently marketed new drugs and biologicals compares to MedPAC's findings. Although the number of new drugs that are priced using WAC is very limited, the average difference between WAC and ASP-based payment limits for a group of 3 recently approved drugs and biologicals that appeared on the ASP Drug Pricing Files (including one biosimilar biological product) was 9.0 percent. Excluding the biosimilar biological product results in a difference of 3.5 percent. The difference was determined by comparing a partial quarter WAC-based payment amount determined under section 1847A(c)(4) of the Act to the next quarter's ASP-based payment amount. These findings are in general agreement with MedPAC's findings.

Although we are able to provide examples of the relative differences between ASP and WAC based payment limits, and we anticipate some savings from the proposals, we cannot estimate the magnitude of savings over time because we cannot determine how many new drugs and biologicals subject to partial quarter pricing will appear on the ASP Drug Pricing files in the future or how many Part B claims for these products will be paid. This limitation also applies to contractor-priced drugs and biologicals that have HCPCS codes and are in their first quarter of sales. Finally, the claims volume for contractor-priced drugs and biologicals that are billed using miscellaneous or Not Otherwise Classified codes, such as J3490 and J3590, cannot be quantified. We would like to note that for the three drugs discussed in the preceding paragraph, Medicare Part B payments for individual doses of each drug range from approximately \$3,000 to \$10,000. The payment changes proposed in this rule would have resulted in a little less than \$100 to \$300 savings in Medicare allowed charges for each dose.

Although we cannot estimate the overall savings to the Medicare Program

or to beneficiaries, we would like to point out that this change in policy is likely to decrease copayments for individual beneficiaries who are prescribed new drugs. Given that launch prices for single doses for some new drugs may range from tens to hundreds of thousands of dollars, a 3 percentage point reduction in the total payment allowance will reduce a patient's 20 percent Medicare Part B copayment. This proposed approach can result in savings to an individual beneficiary and can help Medicare beneficiaries afford to pay for new drugs by reducing out of pocket expenses.

The 3 percent add-on is expected to reduce the difference between acquisition cost and certain WAC-based Part B drug payments, creating greater parity between the two. Based on MedPAC's June 2017 Report to Congress, we do not anticipate that this change will result in payments amounts that are below acquisition cost or that the proposals will impair providers' or patients' access to Part B drugs.

2. Proposed Changes to the Regulations Associated With the Ambulance Fee Schedule

As discussed in section III B.2. of this proposed rule, section 50203(a) of the Bipartisan Budget Act of 2018 amended section 1834(l)(12)(A) and (l)(13)(A) of the Act to extend the payment add-ons set forth in those subsections through December 31, 2022. The ambulance extender provisions are enacted through legislation that is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there are no policy proposals associated with these legislative provisions or associated impact in this rule. We are proposing only to revise the dates in § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

In addition, as discussed in section III.B. 3. of this proposed rule, section 53108 of the BBA amended section 1834(l)(15) of the Act to increase the payment reduction from 10 percent to 23 percent effective for ambulance services furnished on or after October 1, 2018 consisting of non-emergency basic life support services (BLS) involving transports of an individual with end stage renal disease for renal dialysis services furnished other than on an emergency basis by a provider of services or a renal dialysis facility. The 10 percent reduction applies for such ambulance services furnished during

the period beginning on October 1, 2013 and ending on September 30, 2018.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate decrease and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there are no policy proposals associated with these legislative provisions or associated impact in this rule. We are proposing to revise § 414.610(c)(8) to conform the regulations to this self-implementing statutory requirement.

3. Clinical Laboratory Fee Schedule: Proposed Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory

As discussed in section III.A. of this proposed rule, section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. The CLFS final rule titled, Medicare Clinical Diagnostic Laboratory Tests Payment System final rule (CLFS final rule), published in the June 23, 2016 **Federal Register**, implemented section 1834A of the Act. Under the CLFS final rule (81 FR 41036), "reporting entities" must report to CMS during a "data reporting period" "applicable information" (that is, certain private payor data) collected during a "data collection period" for their component "applicable laboratories." In general, the payment amount for each clinical diagnostic laboratory test (CDLT) on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the 6-month data collection period and reported to us during the 3-month data reporting period, and is equal to the weighted median of the private payor rates for the CDLT.

An applicable laboratory is defined at § 414.502, in part, as an entity that is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA) definition at § 493.2) that bills Medicare Part B under its own National Provider Identifier (NPI). In addition, an applicable laboratory is an entity that receives more than 50 percent of its Medicare revenues during a data collection period from the CLFS and/or the PFS. We refer to this component of the applicable laboratory definition as the "majority of Medicare revenues threshold." The definition of applicable laboratory also includes a "low expenditure threshold" component which requires an entity to receive at least \$12,500 of its Medicare revenues

from the CLFS during a data collection period, for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs).

In determining payment rates under the private payor rate-based CLFS, one of our objectives is to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts, for example, from independent laboratories, hospital outreach laboratories, and physician office laboratories, without imposing undue burden on those entities. We believe it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT, and minimizing the reporting burden for entities. In response to stakeholder feedback and in the interest of facilitating our goal, we are proposing to revise the majority of Medicare revenues threshold component of the definition of applicable laboratory at § 414.502(3) to exclude Medicare Advantage payments under Medicare Part C from the definition of total Medicare revenues (that is, the denominator of the majority of Medicare threshold equation). This change would permit laboratories with a significant Medicare Part C revenue component to meet the majority of Medicare revenues threshold and potentially qualify as an applicable laboratory (if it also meets the low expenditure threshold). As a result, a broader representation of the laboratory industry may report applicable information from which to determine

payment rates under the CLFS. For a complete discussion of our proposal to revise the majority of Medicare revenues threshold component of the definition of applicable laboratory under the Medicare CLFS, we refer readers to section III A. of this proposed rule.

a. Estimation of Increased Reporting

To estimate the potential impact of excluding Medicare Advantage plan payments from total Medicare revenues (that is, the denominator of the low expenditure threshold) on the number of laboratories meeting the majority of Medicare revenues threshold, using CY 2017 Medicare claims data, we compared the number of billing NPIs that would have met the majority of Medicare revenues threshold with Medicare Advantage plan revenues included in total Medicare revenues (which is the current requirement) versus the number of billing NPIs that would meet the majority of Medicare revenues threshold had Medicare Advantage plan payments been *excluded* from total Medicare revenues (which is the proposed change). We found that excluding Medicare Advantage plan payments from total Medicare revenues increased the level of laboratories meeting the majority of Medicare revenues threshold by approximately 43 percent. In other words, we estimate that excluding Medicare Advantage plan payments from total Medicare revenues (the denominator) of the majority of Medicare revenues threshold, and keeping the numerator constant (that is revenues from only the CLFS and or PFS) yields an increase of 43 percent in

the number of laboratories meeting the majority of Medicare revenues threshold.

As discussed on the CLFS website, our summary analysis of data reporting from the initial data reporting period under the Medicare CLFS private payor rate-based payment system, indicated that we received applicable information from 1,942 applicable laboratories reporting over 4.9 million records. Applying the projected 43 percent increase to the number of applicable laboratories from the first data reporting period ($1,942 \times 1.43$) yields an estimated 2,777 laboratories that would meet the majority of Medicare revenues threshold, which reflects an additional 835 laboratories. Provided all other required criteria for applicable laboratory status are met (including the low expenditure threshold of receiving at least \$12,500 in CLFS revenues during a data collection period) a laboratory would report applicable information for the next data reporting period.

To determine the estimated reporting burden for an applicable laboratory, we looked at the distribution of reported records that occurred for the first data reporting period. The average number of records reported for an applicable laboratory for the first data reporting period was 2,573. The largest amount of records reported for an applicable laboratory was 457,585 while the smallest amount reported was 1 record. A summary of the distribution of reported records from the first data collection period is illustrated in Table 95.

TABLE 95—SUMMARY OF RECORDS REPORTED FOR FIRST DATA REPORTING PERIOD

[By applicable laboratory]

Total records	Average records	Min records	Max records	Percentile distribution of records				
				10th	25th	50th	75th	90th
4,995,877	2,573	1	457,585	23	79	294	1,345	4,884

Presuming that all of the additional laboratories that are projected to meet the majority of Medicare revenues threshold, that is approximately 835, also meet all of the criteria necessary to receive applicable laboratory status, as defined at § 414.502, they would be an applicable laboratory and report applicable information for the next data reporting period, January 1, 2020 through March 31, 2020. Using the mid-point of the percentile distribution of reported records from the initial data reporting period, that is approximately 300 records reported per applicable

laboratory (50th percentile for the first data reporting period was 294), we estimate an additional 250,500 records would be reported for the next data reporting period ($835 \text{ laboratories} \times 300 \text{ records per laboratory} = 250,500$). This represents an increase in data reporting of about 5 percent over the number of records reported for the initial data reporting period ($250,500 \text{ additional records} / 4,995,877 = .05$). In other words, using the approximate mid-point of reported records for the first data reporting period, we estimate that our proposed change to the majority of

Medicare revenues threshold would increase the total amount of records reported by approximately 5 percent. As illustrated in Table 95, the number of records reported varies greatly, depending on the volume of services performed by a given laboratory. Laboratories with larger test volumes, for instance at the 90th percentile, should expect to report more records as compared to the midpoint used for this analysis. Likewise, laboratories with smaller test volume, for instance at the 10th percentile, should expect to report

less records as compared to the midpoint.

b. Minimal Impact Expected on CLFS Rates

We note that there would only be an associated Medicare cost or savings to the extent that the additional applicable laboratories are paid at a higher (or lower) private payor rate, as compared to other laboratories that reported previously *and* to the extent that the volume of services performed by these “additional” applicable laboratories is significant enough to make an impact on the weighted median of private payor rates. We have no reason to believe that increasing the level of participation would result in a measurable cost difference under the CLFS. Given that the largest laboratories with the highest test volumes, by definition, dominate the weighted median of private payor rates, and the largest laboratories reported data for the determination of CY 2018 CLFS rates and are expected to report again, we do not expect the additional reported data resulting from our proposed change to the majority of Medicare revenues threshold to have a predictable, direct impact on CLFS rates. However, we believe that this proposal responds directly to stakeholder concerns regarding the number of applicable laboratories reporting applicable information for the initial data reporting period. Therefore, in an effort to increase the number of laboratories qualifying for applicable laboratory status, we are proposing a change to the majority of Medicare revenues threshold so that laboratories furnishing tests to a significant level of Medicare Part C enrollees may qualify as applicable laboratories and report data to us.

4. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The CY 2016 PFS final rule with comment period established an evidence-based process and transparency requirements for the development of AUC and stated that the AUC development process requirements, as well as the application process that organizations must comply with to become qualified PLEs did not impact CY 2016 physician payments under the PFS (80 FR 71362). The CY 2017 PFS final rule identified the requirements CDSMs must meet for qualification and stated that the CDSM requirements, as well as the application process that CDSM developers must comply with for their mechanisms to be specified as qualified under this program, did not impact CY 2017 physician payments under the PFS (81

FR 80546). The CY 2018 PFS rule finalized the effective date of January 1, 2020, on which the AUC consulting and reporting requirements will begin, and extended the voluntary consulting and reporting period to 18 months. Therefore, we stated these proposals did not impact CY 2018 physician payments under the PFS (82 FR 53349) and noted we would provide an impact statement when applicable in future rulemaking.

This proposed rule includes proposals to modify the Medicare AUC Program and addresses the impacts related to the actions taken by ordering professionals who order advanced diagnostic imaging services and those who furnish the professional and technical components of advanced diagnostic imaging services. The proposed rule proposes to modify the consultation requirement in § 414.94(j); therefore, this analysis estimates the impact of consultations by ordering professionals. The proposed rule proposes to clarify the reporting requirement in § 414.94(k), and this analysis estimates the impact of reporting AUC consultation information. The proposed rule also proposes to modify the significant hardship exceptions in § 414.94(i), therefore this analysis estimates the impact of a self-attestation process for ordering professionals. We also estimate the further reaching impacts of the AUC program in the detailed analysis that follows, assuming that some ordering professionals will purchase a qualified CDSM integrated within their existing EHR and others may purchase an EHR system in order to obtain an integrated qualified CDSM. We believe that in the beginning of this program due to the additional action required on the part of the ordering professional, it may take longer for a Medicare beneficiary to obtain an order for an advanced diagnostic imaging service, and therefore, we have calculated an estimated impact to Medicare beneficiaries.

This proposed rule discusses options to report the required claims-based AUC consultation information required in § 414.94(g)(1)(iv)(B) and we estimate the impact of our proposal to use existing coding methods (G-codes and HCPCS modifiers) to report that information. Finally, we measure the estimated impact on furnishing professionals and facilities of the proposed expansion of the definition of applicable setting in § 414.94(b). While the consultation and reporting requirements of this program are effective beginning January 1, 2020 with an Educational and Operations Testing Period, we attempt in this analysis to identify areas of potential

qualitative benefits to both Medicare beneficiaries and the Medicare program.

a. Impact of Consultations by Ordering Professionals

In this proposed rule, we are proposing modifications to the AUC program largely in response to public comments and recommendations as we believe these modifications are also important in minimizing burden of the AUC program on ordering professionals, furnishing professionals, and facilities. Specifically, we include a proposal regarding who, when not personally performed by the ordering professional, may consult AUC through a qualified CDSM and still meet the requirements of our regulations. In the CY 2018 PFS final rule, we estimated the consulting requirement based on the 2 minute effort of a family and general practitioner to result in an annual burden of 1,425,000 hours (43,181,818 consultations (Part B analytics 2014 claims data) \times 0.033 hr/consultation) at a cost of \$275,139,000 (82 FR 53349).

An important difference from last year's analysis is that this year's analysis includes estimates for non-physician practitioners that order advanced diagnostic imaging services. For the purposes of this analysis, we assume that orders for advanced diagnostic imaging services would be placed by ordering professionals that are non-physician practitioners in the same percent as the numbers of non-physician practitioners are relative to the total number of non-institutional providers. Therefore, this analysis assumes that 40 percent of all advanced diagnostic imaging services would be ordered by non-physician practitioners. While non-physician practitioners may not order advanced diagnostic imaging services in the same proportion as their numbers, we did not have other data to use for this estimate. We specifically solicit comment and data on alternative assumptions about the number of non-physician practitioners who order advanced imaging services.

In addition, in this proposed rule we propose that auxiliary personnel may perform the AUC consultation when under the direction of, and incident to, the ordering professional's services. Due to this proposed change, we estimate that the majority, or as many as 90 percent, of practices would employ the use of auxiliary personnel, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation for advanced diagnostic imaging orders. We also considered leaving the policy unchanged, and smaller modifications to that could expand who performs the

consultation to a single type of non-physician practitioner. However, we believe this proposal maximizes burden reduction effort as illustrated in the following updated estimate of consultation burden.

To estimate the burden of this modification, we calculated the effort of a 2-minute consultation with a qualified CDSM by a registered nurse (occupation code 29–1141) with mean hourly wage of \$35.36 and 100 percent fringe benefits to be \$2.33/consultation ($\$35.36/\text{hour} \times 2 \times 0.033 \text{ hour}$). If 90 percent of consultations (1,282,500 hours) are performed by such auxiliary personnel then annually the burden estimate would be \$90,698,400 ($1,282,500 \text{ hours} \times \$70.72/\text{hour}$) for auxiliary personnel to consult. We acknowledge that some AUC consultations will not be performed by other auxiliary personnel, therefore the remaining total annual burden we estimate is \$31,810,275 for this proposed consultation requirement. As a result of these assumptions and calculations, we estimate a reduction in consultation burden from cost of \$275,139,000 to \$122,508,675, which results in a proposed net burden reduction of \$152,630,325.

b. Impact of Significant Hardship Exceptions for Ordering Professionals

We previously identified exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services (81 FR 80170). Our original intention was to design the AUC hardship exception process in alignment with the EHR Incentive Program and then the MIPS ACI performance category (now promoting interoperability). However, in this proposed rule, we propose to modify the significant hardship exception criteria under § 414.94(i)(3) to be specific to the Medicare AUC program and independent of other Medicare programs both in policy and process. Specifically, we are proposing that all ordering professionals self-attest if they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order. Since the Medicare EHR Incentive Program has ended and we are unable to continue incorporating regulation that is no longer in effect, we did not consider leaving this policy unchanged. We also considered using a hardship application submission process. However, we believe that this proposed self-attestation process maximizes burden reduction effort as illustrated in the following updated estimate of

ordering professionals subject to a consultation burden.

To estimate the impact of our proposal to modify this section and create a hardship exception specific to this program we attempted to identify how many ordering professionals would be subject to this program.

Medicare non-institutional Part B claims for the first 6 months of 2014 shows that for claims for an advanced diagnostic imaging service that listed an NPI for the ordering/referring provider, up to 90-percent of claims include only 18 different provider specialties. These specialties include: Emergency Medicine; Internal Medicine; Family Practice; Cardiology; Hematology/Oncology; Orthopedic Surgery; Neurology; Urology; Physician Assistant; Nurse Practitioner; Pulmonary Disease; General Surgery; Neurosurgery; Medical Oncology; Gastroenterology; Radiation Oncology; Otolaryngology; and Diagnostic Radiology. We then used CMS data that served to create Table II.8 of the 2014 Medicare Statistics Book and were able to identify how many practitioners in each of those specialties were participating in Medicare program. Table II.8 of the 2014 Medicare Statistics Book combines many of these specialties into higher level groupings and displays the total number of practitioners participating in the Medicare program. However, we used more granular information that identifies the number of practitioners participating in the Medicare program by an individual specialty rather than higher level groupings (table available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2016/Downloads/PROVIDERS/2016_CPS_MDCR_PROVIDERS_6.pdf). For example, Table II.8 of the 2014 Medicare Statistics Book combines all surgeons into one category whereas we used detailed information for the individual surgical specialties of general surgery and orthopedic surgery for this estimate.

Using this more specific data for the 18 specialties, we estimate the count of practitioners that will be ordering professionals under the AUC program to be 586,386. There are limitations as we do not have data on the actual number of practitioners who order advanced diagnostic imaging services because information about the ordering professional is not required to be included on the Medicare claim form for advanced diagnostic imaging services.

In the absence of data on the breadth of professionals who would be required

to consult AUC, we assumed that professionals in the specialties listed earlier could potentially be subject to these requirements because some professionals within a specialty may order these imaging services. We specifically request comments and data on the numbers of professionals in the specialties that actually order advanced imaging services.

With respect to the hardship exception, based on 2016 data from the Medicare EHR Incentive Program and the 2019 payment year MIPS eligibility and special status file, we estimated that 6,699 respondents in the form of eligible clinicians, groups, or virtual groups will submit a request for a reweighting to zero for the advancing care information performance category due to extreme and uncontrollable circumstances or as a result of a decertification of an EHR. For the purposes of this analysis, we cautiously estimate that each of the 6,699 respondents represents a unique ordering professional and that all respondents who experience extreme and uncontrollable circumstances or have an EHR that is decertified are ordering professionals who would self-attest to a significant hardship exception under the AUC program. Nevertheless, we have used this information to update our estimate that there are 579,687 ordering professionals subject to this program.

We believe that the proposed significant hardship exception at § 414.94(i) would further reduce the burden of this program if finalized for four reasons. First, due to the availability of a significant hardship exception there will likely be fewer ordering professionals consulting specified applicable AUC. Second, the self-attestation process is a less burdensome proposal when compared to the alternative of a hardship application process that may have both regulatory impact and information collection requirements. Third, any application or case-by-case determination would necessitate immediate infrastructure development by CMS directly or through one or more Medicare Administrative Contractors (MACs), which adds burden and impact to this program. Finally, the proposed self-attestation process requires no verification on the part of the furnishing professional or facility required to report AUC consultation information on the Medicare claim, thus minimizing burden for both ordering professionals, furnishing professionals and facilities. While some of the efficiencies gained from a self-attestation process are qualitative in nature and difficult to measure, such as the streamlined

reporting, we believe that relative to other regulatory approaches this proposal uses a least burdensome approach.

We recognize that ordering professionals would store documentation supporting the self-attestation of a significant hardship. Storage of this information could involve the use of automated, electronic, or other forms of information technology at the discretion of the ordering professional. We estimate that the average time for office clerical activities associated with this task to be 10 minutes. To estimate the burden of this storage, we expect that a BLS occupation title 43–6013 Medical Secretary with a mean hourly rate of \$17.25 and 100-percent fringe benefits would result in a calculated effort of 10 minutes of clerical work to be \$5.76 ($\$17.25/\text{hour} \times 2 \times 0.167 \text{ hour}$). If 6,699 separate ordering professionals require that a Medical Secretary perform the same clerical activity on an annual basis, then this equates to a cost of approximately \$38,596 per year. We seek comment to inform these burden estimates.

c. Impact of Consultations Beyond the Impact to Ordering Professionals

While we have already discussed the time and effort to consult specified applicable AUC through a qualified CDSM here and in previous rulemaking (81 FR 80170), we believe the impact of this program is extensive as it will apply to every advanced diagnostic imaging service (for example, magnetic resonance imaging (MRI), computed tomography (CT) or positron emission tomography (PET)) and crosses almost every medical specialty. Therefore, we also have described in this detailed analysis the impacts of AUC consultation beyond the act of consulting specified applicable AUC.

(1) Transfers From Ordering Professionals to Qualified CDSMs and EHR Systems

The first additional impact we identified is upstream in the workflow of the AUC consultation and represents the acquisition cost, training, and maintenance of a qualified CDSM. These tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4)) of the Act or private sector mechanisms independent from certified EHR technology or established by the Secretary. Currently, none are established by the Secretary. Additionally, for the purposes of this program, as required by statute, one or more of such mechanisms is available

free of charge. For this impact analysis we will assume three potential scenarios as low, medium, and higher burden assessments of this consultation requirement. First, we assume that some number of ordering professionals consults a qualified CDSM available free of charge. Second, we assume that some number purchase a qualified CDSM to integrate within an existing EHR system. Third, we assume that some do not currently have an EHR system and, as a result of the statutory requirement to consult with AUC, would purchase an EHR system with an integrated qualified CDSM to consult specified applicable AUC for the purposes of this program.

In the lowest estimate of burden, every AUC consultation would take place using a qualified CDSM available free of charge integrated into an EHR system and add no additional cost to the requirement in § 414.94(j) of this proposed rule. While we did not base this estimate on absolute behaviors by all those who have ordered advanced diagnostic imaging services, we believe it is reasonable to estimate that as many as 75 percent of an assumed annual 40,000,000 orders for advanced diagnostic imaging services could occur at no additional cost beyond the time and effort to perform the consultation.

In contrast, some ordering professionals may choose to purchase a qualified CDSM that is integrated within their EHR. To estimate how many ordering professionals may choose to purchase an integrated qualified CDSM, we consulted the 2015 National Electronic Health Records Survey⁴⁷ (NEHRS), which is conducted by the National Center for Health Statistics (NCHS) and sponsored by the Office of the National Coordinator for Health Information Technology (ONC). NEHRS is a nationally representative mixed mode survey of office-based physicians that collects information on physician and practice characteristics, including the adoption and use of EHR systems. In the United States in 2015, 86.9 percent of office-based physicians used any EHR/EMR, with significantly higher adoption by general or family practice physicians (92.7 percent, $p\text{-value} < 0.05$), and slightly lower for medical non-primary care physicians (84.4 percent). Given that approximately 87 percent of office-based physicians have adopted EHR systems, we believe it is likely that the majority will prefer a qualified CDSM integrated with EHR. While we note that qualified CDSMs available free

of charge are also integrated within one or more EHR systems, the following exercise estimates the time and effort to purchase, install, train, and maintain a qualified CDSM integrated into an EHR system.

Again, as stated above, we do not have data on the number of clinicians who order advanced diagnostic imaging services, and we have made overarching assumptions to look at particular specialty areas that in our claims analysis order these advanced diagnostic imaging services. We assumed all individual clinicians in these specialty areas could potentially be subject to these requirements. Adding the number of clinicians in each of the specialty areas results in 586,386 ordering professionals. We also did not make a distinction between individual professionals and groups, as further explained below.

To calculate the impact of a single purchase, we believe that ordering professionals, either in groups or individually, would spend an estimated \$15,000 for a one-time purchase of an integrated qualified CDSM, including installation and training. We assume that all of these costs are based on market research and incurred over the course of 5 years. We also assume that the \$15,000 purchase would be made by each ordering professional and did not take into account the potential that a group practice might incur a discounted price per user based on the number of ordering professionals in the practice. These assumptions could significantly alter the impact estimate and we seek comment on such assumptions.

Given the difficult nature of deriving these estimates based on limited data, we solicit comment and information on the preference that physicians and practitioners might have for using an integrated qualified CDSM—a free CDSM or a CDSM that is not free but integrated within an existing EHR system. Also, if purchased, whether this would be purchased at the group practice level to be made available to all clinicians in the practice for the same cost that would be incurred by a single practitioner purchasing the same qualified CDSM, and whether the cost of purchasing a CDSM would be incurred in a single year or over multiple years.

For the purposes of estimating the transfer of costs from ordering professionals to qualified CDSM developers, of the estimated 579,687 practitioners that are likely subject to this program, we excluded 181,653 ordering professionals with specialties whose practitioners order on average fewer than 20 advanced diagnostic imaging services per year (physician

⁴⁷ Jamoom E, Yang N. Table of Electronic Health Record Adoption and Use among Office-based Physicians in the U.S., by State: 2015 National Electronic Health Records Survey. 2016.

assistant, nurse practitioner, and diagnostic radiology). The assumption is that lower volume ordering professionals would select a qualified CDSM that is free of charge. This updates the estimate to consider 398,034 ordering professionals who may purchase an integrated qualified CDSM. To this end, if we assume 346,290 (398,034 ordering professionals \times 87 percent) ordering professionals already have an EHR system and 30 percent of these ordering professionals (346,290 \times 30 percent, or 103,887) make this purchase for \$15,000 and spend \$1,000 annually to maintain their system for 5 years (initial acquisition cost in year 1 and maintenance costs in years 2–5), then the total annual cost is estimated to be \$394,770,600 ((103,887 \times \$19,000)/5 years)).

It is also reasonable to assume that some ordering professionals may not need additional training in using a qualified CDSM because the EHR Incentive Program required CDS as a core measure. In addition, the program incentivized use of computerized provider order entry (CPOE)—an electronic submission of pharmacy, laboratory, or radiology orders. To determine readiness among Medicare practitioners for these and other measures, the 2011 Meaningful Use Census⁴⁸ (RTI International, 2012) observed that those participating in the EHR Incentive Program in 2011 on average met and exceeded the established 30 percent threshold for meaningful use of CPOE in Stage 1. Analysis of the distribution of performance on these measures shows that 86 percent of eligible participants were well over the established thresholds. It is important to note that the CPOE measure had a higher threshold in Stage 2, and 60 percent of eligible participants in 2011 attested to meaningful use are already meeting this higher threshold. This report suggests that some ordering professionals may be well prepared to adopt a qualified clinical decision support mechanism, as this experience offset may yield lower costs and burden to learn to incorporate decision support into the ordering workflow through shorter training times.

Additionally, some ordering professionals may choose to purchase a certified EHR system to use a qualified CDSM already integrated within the EHR. The first estimate of capital costs for certified EHR system was identified in the first year of the EHR incentive

program as an estimated cost of approximately \$54,000 (75 FR 44518), which adjusted for inflation using the Consumer Price Index for All Urban Consumers (CPI-U) U.S. city average series for all items, not seasonally adjusted, represents \$62,050.40 in 2018. If we assume that 346,290 ordering professionals subject to this program have adopted EHR, then we will also assume that 51,744 ordering professionals (398,034 ordering professionals \times 13 percent) have not adopted an EHR system.

Most physicians who have not yet invested in the hardware, software, testing, and training to implement EHRs may continue to work outside the EHR for a number of reasons—lack of standards, lack of interoperability, limited physician acceptance among their peers, maintenance costs, and lack of capital. Adoption of EHR technology necessitates major changes in business processes and practices throughout a provider's office or facility. Business process reengineering on such a scale is not undertaken lightly. Therefore, while we cannot estimate the business decisions of all ordering professionals, we assume for the purposes of this analysis that as a result of this program some ordering professionals will purchase an EHR system in order to access a qualified CDSM that is integrated into that EHR system for the purposes of acquiring long-term process efficiencies in consulting specified applicable AUC.

We do not have data on the characteristics of physicians who have not purchased an EHR system. However, for the purpose of estimating the transfer of costs from ordering professionals to EHR systems, we will assume based on research from business advisors⁴⁹ that 30 percent, or 15,523 ordering professionals (51,744 ordering professionals \times 30 percent) will seek to purchase an EHR system at an estimated cost of \$62,050.40 for a total one-time cost of \$963,208,359.20 in EHR system and integrated qualified CDSM infrastructure. As we believe not every ordering professional in this example would purchase such infrastructure immediately, for the purposes of this estimate, we annualized this cost over 5 years to \$192,641,671.84/year. We recognize that qualified CDSMs may be modules within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from

certified EHR technology or established by the Secretary.

These estimates are highly sensitive to our assumptions of both the percent of physicians who would purchase an EHR system as a result of this program and the costs of an EHR system. We recognize that due to the limited data available to make these assumptions our estimates are likely high and we seek comment and information about these assumptions. These estimates might be viewed as an upper bound of the impact of this program beyond consultation with a free tool and note that at the time of publication there were three free tools available as indicated on the CMS website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html>.

(2) Impact to Medicare Beneficiaries

Additionally, we believe that the additional 2-minute consultation will impact the Medicare beneficiary when their advanced diagnostic imaging service is ordered by the ordering professional by introducing additional time to their office visit. To estimate this annual cost, we multiplied the annual burden of 1,425,000 hours by the BLS occupation code that represents all occupations in the BLS (00–0000) as mean hourly wage plus 100 percent fringe (\$47.72/hr) for a total estimate of \$68,001,000 per year. Over time, there may be process efficiencies implemented in one or more practices similar to the benefits of deploying CDS⁵⁰ (Berner, 2009; Karsh, 2009) that decrease this estimate. For example, we will assume that every time an advanced diagnostic imaging service is ordered, it is the result of a visit by a Medicare beneficiary for evaluation and management. Then, let us assume that 50 percent of practices implemented an improvement process that streamlined the AUC consultation such that Medicare beneficiaries who visited those practices spent the same amount of time in the physician's office regardless of whether an advanced diagnostic imaging service was ordered. As a result of this improvement process in practice we could estimate such efficiency would offset the estimated burden by \$34,000,500 annually. Although we cannot at this time identify

⁴⁸ Vincent, A. EHR Incentive Program: 2011 Meaningful Use Census. RTI International. November 2012.

⁴⁹ McCormack M, "EHR Software Buyer Report—2014" available at <https://www.softwareadvice.com/resources/ehr-buyer-report-2014/>.

⁵⁰ Berner ES. Clinical decision support systems: State of the Art. AHRQ Publication No. 09–0069–EF. Rockville, Maryland: Agency for Healthcare Research and Quality. June 2009. Karsh B-T. Clinical practice improvement and redesign: how change in workflow can be supported by clinical decision support. AHRQ Publication No. 09–0054–EF. Rockville, Maryland: Agency for Healthcare Research and Quality. June 2009.

a concrete solution, we are seeking comment on this detailed analysis to inform future rulemaking.

d. Considering the Impact of Claims-Based Reporting

In the CY 2018 PFS proposed rule (82 FR 34094), we discussed using a combination of G-codes and modifiers to report the AUC consultation information on the Medicare claim. We received numerous public comments objecting to this potential solution. In the 2018 PFS final rule, we agreed with many of the commenters that additional approaches to reporting AUC consultation information on Medicare claims should be considered, and in the opinion of some commenters, reporting unique consultation identifiers (UCIs) would be a less burdensome and preferred approach. We had the opportunity to engage some stakeholders over the last 6 months and we understand that some commenters from the previous rule continue to be in favor of a UCI. Practically examining the workflow of an order for an advanced diagnostic imaging service before and after implementation of the Medicare AUC program, we see that in general the process remains largely unchanged. Before and after the implementation of this program, an ordering professional could employ support staff to transmit an order for an advanced diagnostic imaging service from his or her office to an imaging facility, physician office, or hospital that furnishes advanced diagnostic imaging services. After implementation of this program, the ordering professionals, furnishing professionals and facilities must adapt this existing workflow to accommodate new information not previously required on orders for advanced diagnostic imaging services.

We considered leaving the policy unchanged, and we also considered writing new regulations requiring larger modifications to the form for manner by which AUC consultation information is communicated from the ordering professional to the furnishing professional or facility. However, we believe the proposal described in this proposed rule minimizes burden and maximizes efficiency by reporting through established coding methods, to include G-codes and modifiers, to report the required AUC information on Medicare claims.

(1) Impact on Transmitting Order for Advanced Diagnostic Imaging Services

We estimate that including AUC consultation information on the order to the furnishing professional or facility is estimated as the additional 5 minutes

spent by a medical secretary (43–6013), at a mean hourly rate of \$17.25 plus 100 percent fringe to transmit the order for the advanced diagnostic imaging service. We believe the estimate of 5 minutes is an estimate that accounts for different transmittal methods, such as through an integrated EHR system, by facsimile, or via telephone call directly to the office of the furnishing professional or facility. In aggregate, if we assume that 40,000,000 advanced diagnostic imaging services are ordered annually, then the total annual burden to communicate additional information in the order is estimated as \$114,540,000 ($\$17.25/\text{hr} \times 2 \times 0.083 \text{ hr} \times 40,000,000 \text{ orders}$).

(2) Impact on CDSM Developers

We believe that in considering a distinct UCI we also considered updating the requirements of a qualified CDSM in § 414.94(g)(1)(vi)(B). This would incur additional costs for the developers of these mechanisms to accommodate formatting changes if instructed by CMS. We continue to believe that participation by CDSM developers in this program is voluntary, that any considerations of proposed changes to this policy maximize benefits and minimize burden to ordering professionals and furnishing professionals and facilities. Internally, CMS has explored the possibility of using a UCI to determine feasibility, and provide a detailed estimate of costs to develop, test, and implement an update in the form and manner of the UCI generated by the CDSM.

To estimate the costs to develop, test, and implement this update, we will provide a relevant case study. In 1998, the Year 2000 Information and Readiness Disclosure Act (Pub. L. 105–271) was passed to ensure continuity of operations in the year 2000. At the time of passage, millions of information technology computer systems, software programs, and semiconductors were not capable of recognizing certain dates after December 31, 1999, and without modification would read dates in the year 2000 and thereafter as if those dates represented the year 1900 or thereafter, or would have failed to process those dates entirely. The federal government had budgeted \$8,300,000,000 to continue processing dates in 2000 and beyond (Department of Commerce, 1999). Additional estimates to repair the date in a form and manner accommodating the year 2000 varied, but one estimate⁵¹ from analysis of the

1998–99 budget bill of the state of California estimated \$241,000,000 to repair 3,000 systems, or \$80,333.33 per system, which adjusted for inflation using the CPI–U, U.S. city average series for all items, not seasonally adjusted, represents \$123,775.95 per system in 2018. If all 16 qualified CDSMs performed an update to the formatting of the UCI to appear on certification or documentation of every AUC consultation, then the one-time total cost incurred by all CDSM developers would be \$1,980,415.20. Although this does not represent a direct transfer of costs from CDSM developers to savings and efficiencies for ordering professionals, furnishing professionals and facilities, we do believe that as a result of such a policy modification that the ordering professional could directly communicate a single AUC UCI, and furnishing professionals and facilities can report UCI in place of identifying each individual CDSM qualified for the purposes of this program.

e. Impact of Expanding Applicable Setting on Furnishing Professionals and Facilities

We expect that an AUC consultation must take place for every applicable imaging service furnished in an applicable setting and paid for under an applicable payment system. In the CY 2017 PFS final rule (81 FR 80170) we codified the definition of applicable setting in § 414.94(b) to include a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. In this proposed rule, we also include a proposal to add independent diagnostic testing facilities to the definition of applicable settings under this program. This proposal is based on the following factors from 2016 CMS Statistics: (1) An independent diagnostic testing facility is independent both of an attending or consulting physician's office and of a hospital; (2) diagnostic procedures when performed by an independent diagnostic testing facility are paid under the PFS; (3) independent facilities have increased 5,120 percent from 4,828 in 1990 to 252,044 in 2015; (4) of those facilities, 1,125 received total payments in excess of \$100,000 in 2015; (5) there were 37,038 radiology non-institutional providers utilized by fee-for-service Medicare beneficiaries for all Part B

⁵¹ LAO Analysis of the 1998–99 Budget Bill Information Technology Issues. Information Technology Issues Analysis of the 1998–99 Budget

Bill. The Year 2000 ("Y2K") Computer Problem. Published February 18, 1998. Accessed March 25, 2018 at http://www.lao.ca.gov/analysis_1998/info_tech_anl98.html.

non-institutional provider services in 2015, of which 14,341 received total payments in excess of \$100,000 in 2015. Taken together, we believe this proposal will result in a more even application of the Medicare AUC program.

To estimate the impact of modifications to this proposal, we assume based on data derived from the CCW's 2014 Part B non-institutional claim line file, which includes services covered by the Part B benefit that were furnished during calendar year 2014, that approximately 40,000,000 advanced diagnostic imaging services are furnished annually, but questioned whether for the purposes of this estimate we should attribute equal weight for these services furnished by each of the following places: (1) A physician's office; (2) a hospital outpatient department; (3) an ambulatory surgical center; and (4) an independent diagnostic testing facility. Therefore, we sought to determine the frequency of advanced diagnostic imaging services furnished by each setting.

For this estimation, we analyzed 2014 Medicare Part B claims data to weight the various applicable settings subject to this program. For this estimate, we analyzed a count of total services furnished for the following 7 Current Procedural Terminology (CPT) codes for advanced diagnostic imaging studies: 70450—computed tomography, head or brain, without contrast material; 74177—computed tomography, abdomen and pelvis, without contrast material; 70553—magnetic resonance (e.g., proton) imaging, brain (including brain stem), without contrast material, followed by contrast material(s) and further sequences; 72148—magnetic resonance (e.g., proton) imaging, spinal canal and contents, lumbar, without contrast material; 78452—Myocardial perfusion imaging, tomographic single-photon emission computed tomography (SPECT) including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed, multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection; 78492—myocardial imaging, positron emission tomography (PET), perfusion, multiple studies at rest and/or stress; 78803—radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s), tomographic SPECT; which represented 10,000,000 total services or approximately a 25 percent sample of the 40,000,000 total advanced

diagnostic imaging services furnished under Part B in 2014.

In this sample, we found the following total services and percent of total services for each of the following settings: (1) Physician's office, 2,997,460 total services, 28.5 percent; (2) hospital outpatient department, 7,465,279 total services, 70.9 percent; (3) ambulatory surgical center, 1,062 total services, 0.01 percent; (4) independent diagnostic testing facility, 58,900 total services, 0.6 percent. We also examined whether the total services furnished in 2015 for each setting increased more than 10 percent from 2014. We found the following total services and percent change from 2014 for each of the following settings: (1) Physician's office, 2,944,144 total services, 2 percent decrease; (2) hospital outpatient department, 7,854,997 total services, 5 percent increase; (3) ambulatory surgical center, 2,900 total services, 173 percent increase; (4) independent diagnostic testing facility, 65,479 total services, 11 percent increase. Taken together, we believe these estimates that attribute 70 percent of all advanced diagnostic imaging services to outpatient, 28 percent to physician's office, and 1 percent each to ambulatory surgical centers and independent diagnostic testing facilities, respectively is generalizable to the total number of visits by Medicare beneficiaries to each of those applicable settings, respectively.

We do not expect that for the purposes of this program furnishing professionals and facilities will need to create new billing practices; however, we assume that the majority of furnishing professionals and facilities will work to alter billing practices through automation processes that accommodate AUC consultation information when furnishing advanced diagnostic imaging services to Medicare beneficiaries. Therefore, we believe a transfer of costs and benefits will be made from furnishing professionals and facilities to medical billing companies to create, test, and implement changes in billing practice for all affected furnishing professionals and facilities.

As mentioned earlier, the 2016 CMS Statistics identified 37,038 radiology non-institutional providers (Table II.8), and 5,470 ambulatory surgical centers (Table II.5) as of December 31, 2015. Because the classification of independent facilities includes both diagnostic radiology and diagnostic laboratory tests, we will assume that 50 percent of the 252,044 facilities existing in 2015 according to 2016 CMS Statistics (126,022 facilities) furnish advanced diagnostic imaging services. The American Hospital Association

Hospital Statistics published in 2018 by Health Forum, an affiliate of the American Hospital Association, identifies the total number of all U.S. registered hospitals to be 5,534. Taken together, we have identified an estimated 174,064 furnishing professionals (37,038 radiologists + 5,470 ASCs + 126,022 independent diagnostic testing facilities + 5,534 hospitals). We will assume for the purposes of this calculation that every identified furnishing professional and facility will choose to update their processes for the purposes of this program in the same way by purchasing an automated solution to reporting AUC consultation information.

The effective date of January 1, 2020 provides some but not extensive time to prepare to update billing processes to accept and report AUC consultation information. Requirements at § 414.94(k) include the following additional information that must be reported: (1) The qualified CDSM consulted by the ordering professional; (2) information indicating whether the service ordered would or would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; (3) the NPI of the ordering professional who consulted specified applicable AUC as required in paragraph (j) of this section, if different from the furnishing professional. Although we are not familiar with any automated billing solution currently available that accommodates this new information, we seek comment on our estimate that based on medical billing and coding for experienced professionals (<http://www.mb-guide.org/>), which provides estimates ranging from \$1,000 to \$50,000 for medical billing software, for the purposes of this calculation such a solution will cost each furnishing professional or facility an estimated \$10,000. We believe this is an estimate based on the assumption that the number of available furnishing professionals and facilities does not equal the number of professionals and facilities furnishing advanced diagnostic imaging services in the Medicare program and although we recognize that more than one furnishing professional or facility may use the same billing service, the combined effectiveness for an automated solution may decrease overall cost. However, this is not an impact on behavior that we could assess before the start of this program and we are seeking feedback on these and other estimates presented. Therefore, given these assumptions, we estimate that the

one-time update will cost \$1,740,640,000 ($174,064 \times \$10,000$).

The Congressional Budget Office estimates that section 218 of the PAMA would save approximately \$200,000,000 in benefit dollars over 10 years from FY 2014 through 2024, which could be the result of identification of outlier ordering professionals and also includes section 218(a) of the PAMA—a payment deduction for computed tomography equipment that is not up to a current technology standard. Because we have not yet proposed a mechanism or calculation for outlier ordering professional identification and prior authorization, we are unable to quantify that impact at this time.

f. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

We believe that the first 5 years of this program will be dedicated to implementation activities, from installation of the technology to training to operational and behavioral changes. Information on the benefits of adopting qualified CDSMs or automating billing practices specifically meeting the requirements in this proposed rule does not yet exist—and information on benefits overall is limited. Nonetheless, we believe there are benefits that can be obtained by ordering professionals, furnishing professionals and facilities, beneficiaries and technology infrastructure developers including qualified CDSM developers, EHR systems developers, and medical billing practices. We describe these estimated benefits in more detail in the following sections.

(1) Estimates of Savings

It has been suggested that one-third of imaging procedures are inappropriate, costing the United States between \$3 billion and \$10 billion annually⁵² (Stein, 2003). Data derived from the CCW 2014 Part B non-institutional claim line file, which includes services covered by the Part B benefit that were furnished during CY 2014, identified approximately \$3,300,000,000 in total payments for advanced diagnostic imaging services. If implementation of this program led to a 30 percent decrease in total payments, then we would expect \$990,000,000 in fewer payments annually. To address this suggestion, the insertion of a pause in the ordering workflow to introduce AUC is a potentially beneficial and cost-effective solution. Some believe⁵³ that

savings could be achieved through the reduction of inappropriate orders, and expenses associated with radiology benefit managers (Hardy, 2010). Indeed, the Institute for Clinical Systems Improvement in Bloomington, Minnesota, performed a clinical decision support pilot project⁵⁴ to (1) improve the utility of diagnostic radiology tests ordered, (2) reduce radiation exposure, (3) increase efficiency, (4) aid in shared decision making, and (5) save Minnesota \$84,000,000 in 3 years (Miliard, 2010). It is hypothesized⁵⁵ that these benefits are the result of educating ordering professionals on the appropriate test for a set of clinical symptoms, rather than just adding time and electronic obstacles between ordering physicians and advanced diagnostic imaging services (Sistrom et al., 2009) as such transfer of knowledge can alter clinical practice.

The Center for Health Care Solutions at Virginia Mason Medical Center in Seattle, Washington examined approaches to control imaging utilization, including external authorization methods and clinical decision support systems. A retrospective cohort study⁵⁶ was performed by Blackmore and colleagues in 2011 of the staged implementation of evidence-based clinical decision support for the following advanced diagnostic imaging services: Lumbar MRI; brain MRI; and sinus CT. Brain CT was included as a control. The number of patients imaged as a proportion of patients with selected clinical conditions before and after the decision support interventions were determined from billing data from a regional health plan and from institutional radiology information systems. The imaging utilization rates after the implementation of clinical decision support resulted in decreases for lumbar MRI (p-value = 0.001), head MRI (p-value = 0.05), and sinus CT (p-value = 0.003), while a decrease in control service head CT was not statistically significant (p-value = 0.88). Although there are limitations to this retrospective claims data analysis, the authors concluded that clinical decision support is associated with large decreases in the

inappropriate utilization of advanced diagnostic imaging services.

It seems reasonable from this and other studies⁵⁷ of local implementation of clinical decision support (Curry and Reed, 2011; Ip et al., 2012) to assume that there may be some savings when regulations become effective January 1, 2020; however, there are also a few hesitations to extrapolating these and other findings broadly to the Medicare population. First, ordering professionals in this program are aware that CMS will pay for advanced diagnostic imaging services that do not adhere to the specified applicable AUC consulted. This awareness may impact the level of interest or extent of behavior modification from exposing ordering professionals to a qualified CDSM. Second, the statute distinguishes between the ordering professional, furnishing professional and facility, recognizing that the professional who orders an applicable imaging service is usually not the same professional or facility reporting to Medicare for that service when furnished. As a result, some ordering professionals may believe that since they are not required to submit AUC consultation information directly to CMS, there are no direct consequences of adhering to specified applicable AUC. Third, many advanced diagnostic imaging services may not have relevant or applicable AUC. Indeed a recent study⁵⁸ implementing CDS was only able to prospectively generate a score for 26 percent and 30 percent of requests for advanced diagnostic imaging services before and after implementation of decision support, respectively (Moriarity et al., 2015). Without AUC available, there can be no decision support intervention into the workflow of the ordering professional. Fourth, even when an ordering professional identifies an advanced diagnostic imaging service recognized as adhering to specified applicable AUC from one qualified PLE, discordance between AUC from different specialty societies has been reported⁵⁹

⁵⁷ Curry, L. and Reed, M.H. Electronic decision support for diagnostic imaging in a primary care setting. *J Am Med Inform Assoc.* 2011; 18: 267–270; Ip, I.K., Schneider, L.I., Hanson, R. et al. Adoption and meaningful use of computerized physician order entry with an integrated clinical decision support system for radiology: Ten-year analysis in an urban teaching hospital. *J Am Coll Radiol.* 2012; 9: 129–136.

⁵⁸ Moriarity, AK, Klochock O, O'Brien M, Halabi S. The Effect of Clinical Decision Support for Advanced Inpatient Imaging. *Journal of American College of Radiology.* 12(4) 2015.

⁵⁹ Winchester DE et al., Discordance Between Appropriate Use Criteria for Nuclear Myocardial Perfusion Imaging from Different Specialty

⁵² Stein C. Code red: Partners program aims to rein in skyrocketing costs of diagnostic imaging. *Boston Globe.* 2003.

⁵³ Hardy, K. Decision Support for Rad Reports. *Radiology Today.* Vol. 11, No. 1, p. 16., 2010.

⁵⁴ Miliard, M. Nuance, ICSI aim to prevent unnecessary imaging tests. *Healthcare IT News.* November 10, 2010.

⁵⁵ Sistrom CL, Dang PA, Weilburg JB, et al., Effect of Computerized Order Entry with Integrated Decision Support on the Growth of Outpatient Procedure Volumes: Seven-year Time Series Analysis. *Radiology.* 251(1), 2009.

⁵⁶ Blackmore, CC; Mecklenburg, RS; Kaplan GS. Effectiveness of Clinical Decision Support in Controlling Inappropriate Imaging. *Journal of the American College of Radiology.* 8(1) 2011.

(Winchester *et al.*, 2016), suggesting that full benefits and savings cannot be realized without standard levels of appropriateness. Taken together, these concerns will form the basis for our continued examination of the impact of this and future rulemaking to maximize the benefits of this program.

(2) Benefits to Medicare Beneficiaries

Although qualified CDSMs are not required to demonstrate that their tools provide measurable benefits, we believe that as a result of installation and use, some ordering professionals may find benefits to the patients they serve. For example, if a qualified CDSM creates a flag or alert to obsolete tests, then the patient will benefit from avoiding unnecessary testing. The same outcome would be likely if a qualified CDSM implemented algorithms that recognize advanced diagnostic imaging services that may produce inaccurate results because of medications being taken by the patient. In addition, if the CDSM provides standardized processes for advanced diagnostic imaging orders or clarification for confusing test names, then the patient benefits from a potential decrease in medical errors. Finally, we believe it is reasonable to assume that some improvements in shared decision making could result from use of a qualified CDSM, because some CDSMs could provide cost information associated with advanced diagnostic imaging services and/or identify situations of repeated testing.

5. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

In the Medicaid Promoting Interoperability Program, to keep eCQM specifications current and minimize complexity, we are proposing to align the eCQMs available for Medicaid EPs in 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period. We anticipate that this proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant as many EPs are expected to report eCQMs to meet the quality performance category of MIPS and therefore should be prepared to report on those eCQMs for 2019. We expect that this proposal would have only a minimal impact on states, by requiring minor adjustments

to state systems for 2019 to maintain current eCQM lists and specifications. State expenditures to make any systems changes required as a result of this proposal would be eligible for ninety percent enhanced Federal financial participation.

For 2019, we are proposing that Medicaid EPs would report on any six eCQMs that are relevant to the EP's scope of practice, including at least one outcome measure, or if no applicable outcome measure is available or relevant, at least one high priority measure, regardless of whether they report via attestation or electronically. This policy would generally align with the MIPS reporting requirement for providers using the eCQM collection type for the quality performance category, which is established in § 414.1335(a)(1). We are also proposing that the eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program would be a full CY in 2019 for EPs who have demonstrated meaningful use in a prior year, in order to align with the corresponding performance period for the quality performance category in MIPS. We continue to align Medicaid Promoting Interoperability Program requirements with requirements for other CMS quality programs, such as MIPS, to the extent practicable, to reduce the burden of reporting different data for separate programs.

In order to help states to make incentive payments to Medicaid EPs by December 31, 2021, consistent with section 1903(t)(4)(A)(iii) of the Act, we are proposing to amend § 495.4 to provide that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program would be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Payments on or before December 31, 2021. Similarly, we are proposing to change the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program to a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Payments on or before December 31, 2021.

We are proposing to allow states the flexibility to set alternative, earlier final deadlines for EHR or eCQM reporting periods for Medicaid EPs in CY 2021, with prior approval from CMS, through their State Medicaid HIT Plan (SMHP).

Providing states with the flexibility to set an alternative, earlier last possible date for the EHR or eCQM reporting period for Medicaid EPs in 2021 would make it easier for states to ensure that all payments are made by the December 31, 2021 deadline, especially for states whose prepayment process may take longer than the 61 days provided by an October 31, 2021 deadline. We expect that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems to meet specifications for the proposed reporting periods, especially because we are also proposing to permit states to set a different end date for all EHR and eCQM reporting periods for Medicaid EPs in 2021. As previously noted, state expenditures for any systems changes required as a result of this proposal would be eligible for 90 percent enhanced Federal financial participation.

Finally, we are proposing changes to the EP Meaningful Use Objective 6, (Coordination of care through patient engagement) Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging), and to EP Meaningful Use Objective 8, Measure 2 (Syndromic surveillance reporting). We are proposing to amend these measures in response to feedback about the burdens they create for EPs seeking to demonstrate meaningful use, and about how they may not be fully aligned with how states and public health agencies collect syndromic surveillance data. These proposed amendments are expected to reduce provider burden. Again, we expect that any changes these proposals might require to state systems would be minimal and that state expenditures to make any such changes would also be eligible for 90 percent enhanced federal financial participation.

6. Medicare Shared Savings Program

We are proposing certain modifications to our rules regarding quality measures. Specifically we are proposing: (1) A policy to add two Patient of Care Experience Survey measures, and (2) a policy to remove four claims-based outcome measures. Both of these proposed policies are generally expected to have a minimal impact on affected ACOs. We do not anticipate any overall impact for these proposed policies because potential individual ACO impacts are more likely to offset one another rather than build to a substantial total in terms of costs or savings.

7. Physician Self-Referral Law

The physician self-referral law provisions are discussed in section III.G. of this proposed rule. We are proposing regulatory updates to implement the provisions of section 50404 of the Bipartisan Budget Act of 2018 pertaining to the writing and signature requirements in certain compensation arrangement exceptions to the statute's referral and billing prohibitions. The proposed regulatory language for the writing requirement reflects current policy, so we do not anticipate that it would have an impact. We expect that the proposal regarding temporary non-compliance with signature arrangements would reduce burden by giving parties additional time to obtain all required signatures.

8. Changes Due to Updates to the Quality Payment Program

In section III.H. of this proposed rule, we included our proposals for the Quality Payment Program. In this section of the proposed rule, we present the overall and incremental impacts to the expected QPs and associated APM incentive payments. In MIPS, we analyze the total impact and incremental impact of statutory changes to eligibility from the Bipartisan Budget Act of 2018 as well as proposals to expand MIPS eligibility by expanding the MIPS eligible clinician definition and adding a third criterion for the low-volume threshold and an opt-in policy option for any clinician that exceeds at least one, but not all, of the low-volume threshold criteria. Finally, we estimate the payment impacts by practice size based on various proposals to modify the MIPS final score, proposals for the performance threshold and additional performance threshold, and as required by the Bipartisan Budget Act of 2018, the impact of applying the MIPS payment adjustments to covered professional services (services for which payment is made under, or is based on, the Physician Fee Schedule and that are furnished by an eligible clinician) rather than items and services covered under Part B.

The submission period for the first MIPS performance period ended in early 2018, however, the final data sets were not available in time to incorporate into this analysis. If technically feasible, we intend to use data from the CY 2017 MIPS performance period in the final rule.

a. Estimated Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

From 2019 through 2024, through the Medicare Option, eligible clinicians receiving a sufficient portion of Medicare Part B payments for covered professional services or seeing a sufficient number of Medicare patients through Advanced APMs as required to become QPs would receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate payment amounts for Medicare covered professional services in the preceding year. In addition, beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs.

The APM Incentive Payment is separate from and in addition to the payment for covered professional services furnished by an eligible clinician during that year. Eligible clinicians who become QPs for a year would not need to report to MIPS and would not receive a MIPS payment adjustment to their Part B physician fee schedule payments. Eligible clinicians who do not become QPs, but meet a slightly lower threshold to become Partial QPs for the year, may elect to report to MIPS and would then be scored under MIPS and receive a MIPS payment adjustment, but do not receive the APM Incentive Payment. For the 2019 Medicare QP Performance Period, we define Partial QPs to be eligible clinicians in Advanced APMs who have at least 40 percent, but less than 50 percent, of their payments for Part B covered professional services through an Advanced APM Entity, or furnish Part B covered professional services to at least 20 percent, but less than 35 percent, of their Medicare beneficiaries through an Advanced APM Entity. If the Partial QP elects to be scored under MIPS, they would be subject to all MIPS requirements and would receive a MIPS payment adjustment. This adjustment may be positive, negative or neutral. If an eligible clinician does not meet either the QP or Partial QP standards, the eligible clinician would be subject to MIPS, would report to MIPS, and would receive the corresponding MIPS payment adjustment.

Beginning in 2026, payment rates for services furnished by clinicians who achieve QP status for a year would be increased each year by 0.75 percent for the year, while payment rates for services furnished by clinicians who do not achieve QP status for the year would be increased by 0.25 percent. In addition, MIPS eligible clinicians would receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B physician fee schedule services in a payment year based on performance during a prior performance period. Although MACRA amendments established overall payment rate and procedure parameters until 2026 and beyond, this impact analysis covers only the third payment year (2021 MIPS payment year) of the Quality Payment Program in detail.

In section III.H.4.g.(4)(b) of this proposed rule, we propose to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity. This option would therefore be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It would also be available to any other TIN for whom all clinicians who have reassigned billing rights to the TIN are participating in a single APM Entity. We are further proposing that this third alternative will only be available to eligible clinicians who meet the Medicare threshold at the APM Entity level; it will not be available for eligible clinicians who meet the Medicare threshold individually.

In section III.H.4.g.(4)(c)(ii), we also propose to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity threshold level. In this scenario, we believe that the Medicare portion of the TIN's All-Payer Combination Option Threshold Score should not be lower than the Medicare Threshold Score that they received by participating in an APM Entity group (82 FR 53881 through 53882). We note this extension of the weighting methodology would only apply to a TIN when that TIN represents a subset of the eligible clinicians in the APM Entity, because when the TIN and the APM Entity are the same there is no need for this weighted methodology. We propose to calculate the TIN's QP Threshold Scores both on its own and with this weighted methodology, and then use the most advantageous score when making a QP determination. We believe that, as

it does for QP determinations made at the APM Entity level, this approach promotes consistency between the Medicare Option and the All-Payer Combination Option to the extent possible. Additionally, the proposed application of this weighting approach in the case of a TIN level QP determination would be consistent with our established policy.

These proposals affect the estimated number of QPs for the 2021 payment year. We estimate that approximately 8,100 additional eligible clinicians in 8 TINs would become QPs if these policies are finalized representing TIN level QP determinations under the All-Payer Combination Option. Therefore, they would be excluded from MIPS, and qualify for the lump sum incentive payment based on 5 percent of their Part B allowable charges for covered professional services, which are estimated to be approximately \$545 million in the 2019 performance year. We also estimate the corresponding increase of the APM incentive payment of 5 percent of Part B allowed charges for QPs would be approximately \$27 million for the 2021 payment year.

Overall, we estimate that between 160,000 and 215,000 eligible clinicians would become QPs, therefore be excluded from MIPS, and qualify for the lump sum incentive payment based on 5 percent of their Part B allowable charges for covered professional services in the preceding year, which are estimated to be between approximately \$12,000 million and \$16,000 million in total for the 2019 performance year. We estimate that the aggregate total of the APM incentive payment of 5 percent of Part B allowed charges for QPs would be between approximately \$600 and \$800 million for the 2021 payment year.

We project the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2019 QP performance period, as well as Advanced APMs anticipated to be operational during the 2019 QP performance period. The projections also reflect an estimated number of eligible clinicians that would attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs in performance year 2019, including the Next Generation ACO Model, Comprehensive Primary Care Plus (CPC+) Model, Comprehensive ESRD Care (CEC) Model (Two-Sided

Risk Arrangement), Vermont All-Payer ACO Model,⁶⁰ Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), Oncology Care Model (Two-Sided Risk Arrangement), Medicare ACO Track 1+ Model, Bundled Payment for Care Improvement Advanced, Maryland Total Cost of Care Model (Maryland Care Redesign Program; Maryland Primary Care Program), and the Shared Savings Program Tracks 2 and 3. We used the APM Participant Lists (see 81 FR 77444 through 77445 for information on the APM participant lists and QP determination) on the most recent MDM provider extract for the Predictive QP determination file for 2018 QP performance period to estimate QPs for the 2019 QP performance period. We examine the extent to which Advanced APM participants would meet the QP thresholds of having at least 50 percent of their Part B covered professional services or at least 35 percent of their Medicare beneficiaries furnished Part B covered professional services through the Advanced APM Entity.

b. Estimated Number of Clinicians Eligible for MIPS Eligibility

(1) Summary of Proposals Related to MIPS Eligibility and Application of MIPS Payment Adjustments

We are making three sets of proposed policy changes that would impact the number of MIPS eligible clinicians starting with CY 2019 MIPS performance period and the CY 2021 MIPS payment year. Two of the proposed changes affect the low-volume threshold and the third affects the definition of a MIPS eligible clinician. We briefly describe each of these changes later in this section.

First, in section III.H.3.c.(2) of this proposed rule, we proposed changes to our policy to comply with the Bipartisan Budget Act of 2018. Specifically, we are proposing to update the low-volume threshold starting with the 2020 MIPS payment year to be based on covered professional services (services for which payment is made under, or is based on the Physician Fee Schedule and that are furnished by an eligible clinician) rather than items and services covered under Part B, as provided in section 1848(q)(1)(B) as amended by section 51003(a)(1)(A)(i) of the Bipartisan Budget Act of 2018. This proposal may affect the previously finalized calculation for the low-volume

threshold for certain clinicians because payment for items, such as Part B drugs, which were previously considered in the low-volume determination, are now excluded. In addition, section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018 revised section 1848(q)(6)(E) to apply the MIPS payment adjustments to covered professional services rather than to items and services covered under Part B. This change is effective with the 2019 MIPS payment year. Its effect on the amount of payment adjustments under MIPS is included in this analysis.

Second, in section III.H.3.a. of this proposed rule, beginning with the 2021 MIPS payment year, we are proposing to expand the definition of MIPS eligible clinicians to include physical therapists, occupational therapists, clinical social workers, and clinical psychologists. Specifically, we are proposing to define as a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, as any of the following: A physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act), a physical therapist, an occupational therapist, a clinical social worker, and a clinical psychologist; and a group that includes such clinicians.

Third, as discussed in sections III.H.3.c.(4) and III.H.3.c.(5) of this proposed rule, in addition to the amendments to comply with Bipartisan Budget Act of 2018, we are proposing to modify our definition of the low-volume threshold by adding a third criterion (for “covered professional services”). If this proposal is finalized, the low-volume threshold would now include a third criterion: Set at 200 covered professional services to Part B-enrolled individuals. Taken together, if this proposal is finalized, the low-volume threshold would be as follows: (1) Those with \$90,000 or less in allowed charges for covered professional services; or (2) 200 or fewer Part B-enrolled individuals who are furnished Medicare physician fee schedule services; or (3) 200 or fewer covered professional services. The low volume threshold assessment is applied at the TIN/NPI level for individual reporting, the TIN level for group reporting, or the APM Entity Level for reporting under the APM scoring standard. We are further proposing any clinician who exceeds the low-volume threshold on at least one, but not all three, low-volume threshold criteria may elect to opt-in to MIPS to be

⁶⁰ Vermont ACOs will be participating in an Advanced APM during 2018 through a modified version of the Next Generation ACO Model. The Vermont Medicare ACO Initiative is expected to be an Advanced APM beginning in 2019.

measured on performance, thereby qualifying to receive a positive, neutral, or negative MIPS payment adjustment based on performance. The absence of the opt-in within this cohort means they are not MIPS eligible clinicians. If a MIPS eligible clinician does not meet at least one of these low-volume criteria, they are excluded from MIPS. For purposes of this impact analysis we refer to these revisions to the low-volume threshold and its application collectively as the “opt-in policy”.

We discuss how these three proposed changes impact MIPS eligibility and payments, later in this section.

(2) Methodology To Assess MIPS Eligibility

(a) Clinicians Included in the Model Prior to Low-Volume Threshold

To estimate the number of clinicians for the CY 2019 performance period, our scoring model used the CY 2019 MIPS payment year eligibility file as described in the CY 2017 Quality Payment Program Final Rule (81 FR 77069 through 77070). We included 1.5 million clinicians (see Table 96) who had Physician Fee Schedule claims from September 1, 2015 to August 31, 2016 and included a 60-day claim run-out. We used data from September 1, 2015 to August 31, 2016 to maximize the overlap with the performance data in our model.

We assessed covered professional services (services for which payment is made under, or is based on the Physician Fee Schedule and that are furnished by an eligible clinician)⁶¹ to understand the incremental impact of basing the low-volume threshold on covered professional services rather than all items and services under Part B.

Clinicians are ineligible for MIPS (and are excluded from MIPS payment adjustment) if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold. Therefore, we excluded these clinicians when calculating those clinicians eligible for MIPS. For our baseline population, we restricted to clinicians who are a physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act). For the proposed MIPS eligible

population for the CY 2021 MIPS payment year, we add in clinicians who are physical therapists, occupational therapists, clinical social workers, and clinical psychologists.

As noted previously, we excluded QPs from our scoring model, since these clinicians are not eligible for MIPS. To determine which QPs should be excluded, we used the APM Participation List for the third snapshot date of the 2017 QP performance period because these data were available by TIN and NPI and could be merged into our model. We assumed that all partial QPs would participate in MIPS and included them in our scoring model and eligibility counts. The estimated number of QPs excluded from our model is lower than the projected number of QPs (160,000 to 215,000) for the 2019 QP performance period due to the expected growth in APM participation. Due to data limitations, we cannot identify specific clinicians who may become QPs in the 2019 Medicare QP Performance Period; hence, our model may overestimate the fraction of clinicians and allowed charges for covered professional services that will remain subject to MIPS after the exclusions.

We also excluded newly enrolled Medicare clinicians from our model. To identify newly enrolled Medicare clinicians, we continued the assumption applied in the CY 2018 Quality Payment Program final rule that clinicians (NPIs) are newly enrolled if they have Physician Fee Schedule charges in the eligibility file but no Physician Fee Schedule charges in 2015. This newly enrolled modeling methodology attempts to simulate those newly enrolled, but does not exactly match the policies finalized under §§ 414.1305 and 414.1310 which uses information from the Provider Enrollment, Chain and Ownership System (PECOS and previous claims submissions).

We also excluded a small percentage of clinicians (20,411) for whom we have limited performance data. Although these clinicians may in fact be eligible for MIPS, we did not have sufficient data to estimate performance.⁶²

In section III.H.3.j.(4)(d) of the proposed rule, we propose to waive the payment consequences (positive, negative or neutral adjustments) of MIPS and to waive the associated MIPS reporting requirements adopted to

implement the payment consequences for certain participating clinicians in the MAQI Demonstration subject to conditions outlined in the Demonstration, starting with the 2020 MIPS payment period. Removing eligible clinicians from MIPS may affect the payment adjustments for other MIPS eligible clinicians in each year the waiver is offered. However, we are unable to identify the specific TIN/NPIs in our model would be affected by this proposal; therefore, we are unable to account for this proposal in the eligibility or payment adjustment tables.

(b) Assumptions Related to the Low-Volume Threshold

The low-volume threshold policy may be applied at the individual (that is, TIN/NPI) or group (that is, TIN or APM entity) levels based on how data are submitted. If no data are submitted, then the low-volume threshold is applied at the TIN/NPI level. We also propose that a clinician or group that exceeds at least one but not all three low-volume threshold criteria may become MIPS eligible by submitting data to MIPS and electing to opt-in, thereby getting measured on performance and receiving a MIPS payment adjustment.

For the purposes of modeling, we made assumptions on group reporting to apply the low-volume threshold. One extreme and unlikely assumption is that no practices elect group reporting and the low-volume threshold would always be applied at the individual level. Although we believe a scenario in which only these clinicians would participate as individuals is unlikely, this assumption is important because it quantifies the minimum number of MIPS eligible clinicians. For the model, we estimate there are approximately 218,000 clinicians who would be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. In Table 96, we identify clinicians under this assumption as having “required eligibility.”

Based on historic data, we anticipate that group and APM Entities will submit data to MIPS. Therefore, if we revise our model’s group reporting assumption such that all clinicians that were participating in ACOs in 2016 (including ACOs participating under the Shared Savings Program, Pioneer ACO Model, or Next Generation ACO Model) or who reported to 2016 PQRS as a group would continue to do so in MIPS, then the MIPS eligible clinician population would increase by almost 390,000 clinicians for a total MIPS eligible population of approximately 608,000. In Table 96, we identify these

⁶¹ The date range for these covered professional services is September 1, 2016 to August 31, 2017.

⁶² We excluded clinicians that submitted via measures groups under the 2016 PQRS, since that data submission mechanism was eliminated under MIPS, and we did not anticipate being able to accurately predict performance. Additionally, we also excluded clinicians in the CPC model if we did not have their quality data.

clinicians who do not meet the low-volume threshold individually but are anticipated to submit to MIPS as a group based on previous participation in legacy programs as having “group eligibility.”

TABLE 96—DESCRIPTION OF MIPS ELIGIBILITY STATUS FOR CY 2021 MIPS PAYMENT YEAR USING THE PROPOSED ASSUMPTIONS ***

Eligibility status	Predicted participation status in MIPS among clinicians *	Number of clinicians	Cumulative number of clinicians
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria).	Participate in MIPS	186,549	186,549
	Do not participate in MIPS	31,921	218,470
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group).	Submit data as a group	389,670	608,140
Opt-In eligibility (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data).	Elect to opt-in and submit data	42,025	** 650,165
Not MIPS eligible:			
Potentially MIPS eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) Meet group eligibility or (2) opt-in eligibility criteria).	Do not opt-in; or Do not submit as a group.	482,574	1,132,739
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria).	Not applicable	88,070	1,220,809
Excluded for other reasons (Non-eligible clinician type, newly-enrolled, QP).	Not applicable	302,172	1,522,981

* Participation in MIPS defined as previously submitting quality or EHR data for PQRS. Our assumptions for group reporting are based on 2016 PQRS group reporting.

** Estimated MIPS Eligible Population.

*** Facility-based eligible clinicians are not modeled separately in this table and are captured in the individual eligible category. This table does not consider the impact of the MAQI Demonstration waiver.

To model the proposed opt-in policy, we assumed that 33 percent of the clinicians who exceed at least one low-volume threshold and submitted data to 2016 PQRS would elect to opt-in to MIPS. We selected a random sample of 33 percent of clinicians without accounting for performance or investment in quality reporting. We believe this assumption of 33 percent is reasonable because some clinicians may choose not to submit data due to performance, practice size, or resources or alternatively, some may submit data, but elect to be a voluntary reporter and not be subject to a MIPS payment adjustment based on their performance. We seek comment on these assumptions, including whether modeling eligibility only among clinicians or groups who submitted at least 6 quality measures to PQRS would be more appropriate. This 33 percent participation assumption is identified in Table 96 as “Opt-In eligibility”. We estimate an additional 42,000 clinicians

would be eligible through this policy for a total MIPS eligible population of approximately 650,000.

There are approximately 482,000 clinicians who are not MIPS eligible, but could be if their practice decides to participate. We describe this group as “Potentially MIPS eligible.” This is the unlikely scenario in which all group practices elect to submit data as a group and all clinicians that could elect to opt-into MIPS do elect to opt-in. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate that the MIPS eligible clinician population could be as high as 1.1 million clinicians.

Finally, there are some clinicians who would not be MIPS eligible either because they are below the low-volume threshold on all three criteria (approximately 88,000) or because they are excluded for other reasons (approximately 302,000).

Since eligibility among some clinicians is contingent on submission to MIPS, we will not know the exact number of MIPS eligible clinicians until the submission period for the CY 2019 MIPS performance period is closed. For this impact analysis, we are using the estimated population of 650,165 MIPS eligible clinicians described above.

(3) Impact of MIPS Eligibility Proposals

We illustrate in Table 97 how each proposed policy for the CY 2021 payment year affects the estimated number of MIPS eligible clinicians. In the CY 2018 Quality Payment Program final rule, 604,006 MIPS eligible clinicians were included in our scoring model (82 FR 53930). After updating the population to exclude the additional QPs identified in the 2017 performance period final QP file, the new baseline population is 591,010. All incremental impact estimates are relative to this baseline.

TABLE 97—INCREMENTAL CHANGE TABLE FOR 2021 MIPS PAYMENT YEAR

Policy changes *	Estimated number of MIPS eligible clinicians impacted by policy change	Estimated effect of policy changes on number of MIPS eligible clinicians	Estimated % change from baseline	Estimated Part B amount paid (mil)	Estimated PFS amount paid (mil)	Estimated % change in PFS from baseline
<i>Baseline:</i> Applying previously finalized policy	N/A	591,010	N/A	54,748	45,163	N/A
<i>Policy Change 1:</i> Low-volume threshold (LVT) determination based on covered professional services (as required by Bipartisan Budget Act of 2018)	– 1,173	589,837	– 0.2	N/A	45,101	– 0.1
<i>Policy Change 2:</i> Expansion of eligible clinician types to include physical therapists, occupational therapists, clinical social workers, and clinical psychologists based with policy change 1	18,303	608,140	2.9	N/A	45,831	1.5
<i>Policy Change 3:</i> Cumulative change of Opt-in Policy with policy changes 1 and 2	42,025	650,165	10.0	N/A	47,401	5.0

* This table does not consider the impact of the MAQI Demonstration waiver.

First, as shown in Table 97, the first row shows the effect of changing the application of the MIPS payment adjustments, as required by section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018 to apply them to covered professional services (services for which payment is made under, or is based on, the Medicare Physician Fee Schedule and are furnished by an eligible clinician) rather than to items and services covered under Part B. As shown, the baseline amount paid for Part B is \$54.7 billion, compared with \$45.1 billion in covered professional services, which is a difference of almost \$10 billion. Under this change, the payment adjustments, beginning in the 2019 MIPS payment year, will only be applied to covered professional services.

In Table 97, under the first policy change, basing the low-volume threshold on covered professional services (services provided under the physician fee schedule rather than items and services covered under Part B) has minimal impact in terms of clinicians (less than half of one percent decrease).

When the second policy change, to expand the definition of MIPS eligible clinician types, was added to the first policy change, the total effect is small. The change in the potential MIPS eligible clinician population increased by less than 3 percent and the amount paid in the Physician Fee Schedule increased by 1.5 percent.

When the third policy change, which implements the opt-in policy, is added to the other two policies, the estimated number of MIPS eligible clinicians increases by 10.0 percent. The estimated

increase in the amount paid in the Physician Fee Schedule is 5.0 percent.

c. Estimated Impacts on Payments to MIPS Eligible Clinicians

(1) Summary of Approach

In sections III.H.3.h., III.H.3.i. and III.H.3.j. of this proposed rule, we are making several proposals which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these proposals in more detail in section VII.F.8.c.(2) as we describe our methodology to estimate MIPS payments for the 2021 MIPS payment year. We note that many of the MIPS policies from the CY 2018 Quality Payment Program final rule were only defined for the 2018 MIPS performance period and 2020 MIPS payment year (including the performance threshold, the additional performance threshold, the policy for redistributing the weights of the performance categories, and many scoring policies for the quality performance category) which precludes us from developing a baseline for the 2019 MIPS performance period and 2021 MIPS payment year if there were no new regulatory action. Therefore, our impact analysis looks at the total effect of the proposed MIPS policy changes on the MIPS final score and payment adjustment for CY 2019 MIPS performance period/CY 2021 MIPS payment year.

The payment impact for an eligible clinician in MIPS is based on their final score, which is a value determined by their performance in the four MIPS performance categories: Quality, cost,

improvement activities, and Promoting Interoperability.

The performance and participation data submitted for the 2017 MIPS performance period were not available in time to estimate the final score and the projected payment adjustments for MIPS eligible clinicians in this proposed rule. Therefore, as discussed in section VII.F.8. of this proposed rule, we used the most recently available data from historic programs. We will use MIPS performance data for the final rule should that data become available.

The estimated payment impacts presented in this proposed rule reflect averages by practice size based on Medicare utilization. The payment impact for a MIPS eligible clinician could vary from the average and would depend on the combination of services that the MIPS eligible clinician furnishes. The average percentage change in total revenues would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; this program does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare Federally Qualified Health Center Prospective Payment System or Medicare Advantage that would not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact

To estimate participation in MIPS for the CY 2019 Quality Payment Program for this proposed rule, we used data

from the 2016 Physician Quality Reporting System (PQRS) and the Medicare and Medicaid EHR Incentive Programs. Our scoring model includes the 650,165 estimated number of MIPS eligible clinicians as described in section VII.F.8.b of this proposed rule.

To estimate the impact of MIPS on eligible clinicians, we used recently available data, including 2015 and 2016 PQRS data, 2015 and 2016 CAHPS for PQRS data, 2016 Quality and Resource Use Reports (QRUR) and 2018 Value Modifier (VM) data, 2016 Medicare and Medicaid EHR Incentive Program data, data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on qpp.cms.gov)⁶³, the 2017 published MIPS measure benchmarks, the APM Participation List for the third snapshot date of the 2017 QP performance period to identify QP clinicians, and other available data to model the scoring provisions described in this regulation. We calculated a hypothetical final score for each MIPS eligible clinician based on quality, cost, Promoting Interoperability, and improvement activities performance categories. Because we lack detailed performance information for virtual groups, we are unable to assess performance for virtual groups as an entity.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using measures submitted to PQRS for the 2016 performance period, the 2016 CAHPS for PQRS data, and the all-cause hospital readmissions measure from the 2016 QRUR/2018 VM analytic file. For quality measures collected via claims, eCQMs, MIPS CQM, QCDR, and CMS-approved survey vendor collection types, we applied the published benchmarks developed for the 2018 MIPS performance period. For quality measures collected and submitted via the CMS Web Interface, we applied the published benchmarks developed for the 2016/2017 reporting years for the Shared Savings Program where available, and did not calculate scores for measures for which Shared Savings Program benchmarks did not exist. For the all-cause hospital readmission measure, we used available published benchmark for CY 2017 MIPS

performance period which is the most recent public benchmark available.

We assigned measure achievement points as finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77282 and 82 FR 53718) and as discussed in section III.H.3.i.(1)(b)(iii) of this proposed rule. As proposed in III.H.3.i.(1)(b)(iii)(A) of this proposed rule, we would continue to apply the 3-point floor for measures that cannot be reliably scored against a baseline benchmark in the 2019 MIPS performance period.

In section III.H.3.h.(2)(b)(iii) of this proposed rule, we propose to remove many measures that were previously able to be reported in PQRS and in previous MIPS performance periods. For our estimates, we assumed that clinicians who reported claims, eCQM, MIPS CQM and QCDR measures that are proposed to be removed would find alternate measures; therefore, we assigned points to these measures and included them in our scoring model. For CY 2019, we maintained the policies for scoring measures that do not meet the quality category requirements (case minimum, benchmark, and data completeness) as described in the CY 2018 Quality Payment Program final rule (82 FR 53727 through 53730). As finalized in the CY 2018 Quality Payment Program final rule, we also applied a 7-point cap for measures that are topped out for two or more years (82 FR 53726 through 53727).

In section III.H.3.h.(2)(a)(iii)(A)(bb) of this proposed rule, we propose to remove several Web Interface measures. For that collection type, which has a standard set of measures, we estimated performance on the measures that we propose to continue.

As proposed in sections III.H.3.i.(1)(b)(ix) and (x) of this proposed rule, we maintained the cap on bonus points for high-priority measures and end-to-end electronic bonus points at 10 percent of the denominator and, beginning with the 2019 MIPS performance period, discontinue high priority bonus points for CMS Web Interface Reporters. Because we are not able to use MIPS performance data in our models at this time, we continued our assumption in the CY 2018 Quality Payment Program final rule to assign the end-to-end electronic bonus: 1 point for every submitted eCQM and for each measure submitted via CMS Web Interface if the group indicated that they submitted using their EHR with a cap of 10 percent of the total possible measure achievement points. To be consistent with our small practice bonus proposal in section III.H.3.i.(1)(b)(viii) of this

proposed rule, we added 3 measure achievement points to the quality performance category score for small practices that had a quality performance category score greater than 0 points.

As finalized in the CY 2018 Quality Payment Program final rule (82 FR 53625 through 52626) and further discussed in III.H.3.h.(2)(a)(iii) of this proposed rule, we are allowing MIPS eligible clinicians and groups to submit data collected via multiple collection types within a performance category beginning with the 2019 performance period. The requirements for the performance categories remain the same regardless of the number of collection types used. We do not apply the validation process that is discussed in section III.H.3.i.(1)(b)(vii) of this proposed rule.

To estimate the impact of improvement for the quality performance category, we estimated a quality performance category percent score using 2015 and 2016 PQRS data, 2015 and 2016 CAHPS for PQRS data, and 2015 and 2016 QRUR data. For eligible clinicians with an estimated quality performance category score less than or equal to a 30 percent score in the previous year, we compared 2019 performance to an assumed 2018 quality score of 30 percent for their improvement score as described in III.H.3.i.(1)(b)(xiii) of this proposed rule.

Due to data limitations, we are unable to model all the policies proposed in this rule. We are not able to incorporate the policy to reduce the denominator for the quality performance category score by 10 points for groups that registered for CAHPS for MIPS but were unable to report due to insufficient sample size as discussed in section III.H.3.i.(1)(b)(iii)(B) of this proposed rule. We also did not apply the proposed scoring policy for measures that are significantly impacted by clinical guideline or other changes discussed in section III.H.3.i.(1)(b)(vi) of this proposed rule.

Our model applied the MIPS APM scoring standards proposed in section III.H.3.h.(6) of this proposed rule to quality data from MIPS eligible clinicians that participated in the Shared Savings Program, the Pioneer ACO Model, and the Next Generation ACO Model in 2016.

(b) Methodology To Estimate the Cost Performance Category Score

In section III.H.3.h.(3)(b) of this proposed rule, we propose to add 8 episode-based measures. For the episode-based measures, we used the proposed episode specifications discussed in section III.H.3.h.(3)(b) of

⁶³ The time period for this eligibility file (September 1, 2015 to August 31, 2016) maximizes the overlap with the performance data in our model.

this proposed rule and claims data from June 2016 through May 2017. We estimated the cost performance category score using the total per capita cost measure (TCPC) and Medicare Spending Per Beneficiary (MSPB) measures from the value modifier (VM) program, as that is the most recently available data, and the 8 newly developed episode-cost measures prepared for MIPS. The values of the 2 VM measures are those computed for the 2018 VM using data from calendar year 2016. Cost measure scores were used only when the associated case size met or exceeded the previously finalized or newly proposed case minimum: 20 for the TCPC measure, 35 for MSPB, 10 for procedural episodes, and 20 for acute medical inpatient medical condition episodes. The VM measures are computed for the TIN; thus, each VM measure score was assigned to each MIPS eligible clinician in the TIN regardless of whether they submit as an individual or as a group. The episode-based measures are computed for both the TIN/NPI and the TIN; these measure scores were assigned to clinicians based on the clinician's submission status, which in this modeling was based on the quality domain. For clinicians participating as individuals, the TIN/NPI level score was used if available and if the minimum case size was met. For clinicians participating as groups, the TIN level score was used, if available, and if the minimum case size was met. For clinicians with no measures meeting the minimum case requirement, we did not estimate a score for the cost performance category, and the weight for the cost performance category was reassigned to the quality performance category. The raw cost measure scores were mapped to scores on the scale of 1–10, using benchmarks developed based on all measures that met the case minimum during the relevant performance period. For the episode-based cost measures, separate benchmarks were developed for TIN/NPI level scores and TIN level scores. For each clinician, a cost performance category score was computed as the average of the measure scores available for the clinician, as described previously.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

As discussed in section III.H.3.i.(1)(d) of this proposed rule, we are implementing facility-based measurement for the 2019 MIPS performance period. In facility-based measurement, we determine the eligible clinician's MIPS score based on Hospital VBP performance score for

eligible clinicians or groups who primarily furnish services within a hospital. Given that we are not requiring eligible clinicians to opt-in to facility-based measurement, it is possible that a MIPS eligible clinician or a group is eligible for facility-based measurement and participates in MIPS as an individual or a group. In these cases, we use the higher combined quality and cost performance category scores.

Data was not available to attribute specific hospital VBP performance score to MIPS eligible clinicians, hence we made the following assumptions. For MIPS eligible clinicians and groups who are eligible for facility-based measurement and who previously submitted quality data to PQRS (which we used to estimate the quality performance category score), we did not estimate a facility-based score. We instead calculated a MIPS quality and cost score based on the available quality measures and cost data. Some clinicians who previously submitted PQRS quality data may receive a higher score through facility-based measurement, but we are unable to identify those clinicians due to data limitations and therefore believe the score based on their submitted data is more likely to reflect their performance.

For MIPS eligible clinicians that did not previously submit data to PQRS and were eligible for facility-based measurement, we estimated a facility-based score by taking the median MIPS quality and cost performance score. We believe it is important to develop an estimate for this cohort because we would have otherwise assigned this group a quality performance category percent score of zero percent which we believe would have underestimated their MIPS final score. Given the data limitations in assigning a specific hospital score to a clinician, we selected the median MIPS quality and cost performance scores as that represents the quality cost performance category scores that a clinician working in a hospital with median performance would receive.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

As discussed in section III.H.3.h.(5)(d)(ii) of this proposed rule, we are proposing to modify the measures and scoring for the Promoting Interoperability performance category score. We proposed to simplify scoring by eliminating the concept of base and performance scores and focusing on a smaller set of measures which are scored on performance. We estimated Promoting Interoperability performance

category scores using data from the CY 2016 Medicare and Medicaid EHR Incentive Programs. Because the EHR Incentive Programs data are based on attestation at the NPI level, the Promoting Interoperability performance category scores are based on the individual level regardless of whether the clinician was part of a group submission or part of an APM entity. We did not calculate a group or APM score for the Promoting Interoperability performance category.

Although we had attestation information for the Medicare EHR Incentive Program, we did not have detailed attestation information for the Medicaid EHR Incentive Program. Therefore, we used incentive payments (excluding incentive payments for the adoption, implementation, and upgrade of CEHRT) as a proxy for attestation for Medicaid EHR Incentive Program participants. To proxy performance, we used the 2016 Medicare EHR Incentive Program data and estimated the median score among Medicare eligible clinicians submitting data for four Promoting Interoperability measures that had data available in the 2016 Medicare EHR Incentive Program. For the e-Prescribing objective, we used the e-Prescribing measure and did not assume any bonus points for the Query of Prescription Drug Monitoring Program (PDMP) or the Verify Opioid Treatment Agreement measures. For the Health Information Exchange objective, we used the Health Information Exchange measure to proxy performance for the two proposed measures in the objective: Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Incorporating Health Information. For the Provider to Patient Exchange objective, we used the Provide Patient Access to View, Download, or Transmit measure to estimate performance for the proposed Provide Patients Electronic Access to Their Health Information measure. For the Public Health and Clinical Data Exchange objective, we assumed that clinicians would meet the proposed reporting requirements and would receive 10 points for the objective. We combined the median scores for each measure, which led to an estimated MIPS Promoting Interoperability performance category median score of 73 points. This estimated MIPS Promoting Interoperability performance category score was applied to all eligible clinicians that attested to participating in the EHR Incentive Programs in our scoring model. The selection of a 73 point Promoting Interoperability

performance category score is lower than the maximum score of 100 percentage points. Our rationale for selecting a 73 point performance category score is that the proposed revision of the Promoting Interoperability criteria would lead to lower scores due to fewer clinicians being able to report measures and achieve maximum performance for the Health Information Exchange Promoting Interoperability Objective. We do not expect all MIPS eligible clinicians participating in MIPS to receive a score of 73 for the Promoting Interoperability performance category; however, we believe this is a reasonable approach given the unavailability of MIPS CY 2017 performance period data in time for this proposed rule. We anticipate using actual MIPS performance period data in the final rule if available in time. We expect that a large proportion of eligible clinicians who submit EHR Incentive Program data will likely achieve a Promoting Interoperability performance category score of 73 points.

For those eligible clinicians who did not attest in either the 2016 Medicare or Medicaid EHR Incentive Program, we evaluated whether the MIPS eligible clinician could have their Promoting Interoperability performance category score reweighted. As finalized in the CY 2017 (81 FR 77069 through 77070) and CY 2018 (82 FR 53625 through 52626) Quality Payment Program final rules, the Promoting Interoperability performance category weight is set equal to 0 percent, and the weight is redistributed to the quality or improvement activities performance category for non-patient facing MIPS eligible clinicians, hospital-based MIPS eligible clinicians, ASC-based MIPS eligible clinicians, or those who request and are approved for a significant hardship or other type of exception, including a significant hardship exception for small practices, or clinicians who are granted an exception based on decertified EHR technology (82 FR 53780 through 53786). We are also proposing in section III.H.3.h.(5)(h) of this proposed rule to continue automatic reweighting for NPs, PAs, CNSs and CRNAs and to add an automatic reweighting policy for physical therapists, occupational therapist, clinical social workers, and clinical psychologists, which we have incorporated into our model. We used the non-patient facing and hospital-based indicators and specialty and small practice indicators as calculated in the initial MIPS eligibility run for the 2017 MIPS performance period (81 FR 77069 through 77070). For significant hardship

exceptions, we used the 2016 final approved significant hardship file from the Medicare EHR Incentive Program. If a MIPS eligible clinician did not attest and did not qualify for a reweighting of their Promoting Interoperability performance category, the Promoting Interoperability performance category score was set to 0 percent.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

We modeled the improvement activities performance category score based on 2016 APM participation and historic participation in 2016 PQRS and 2016 Medicare and Medicaid EHR Incentive Programs. We are not proposing any policy changes that impact scoring for the improvement activities performance category. Our model identified 2016 participants in the Shared Savings Program, Next Generation ACO Model and the Pioneer ACO Model, and assigned them an improvement activity score of 100 percent, consistent with our policy to assign an improvement activities score of 100 percent to ACO participants who were not excluded due to being QPs. Due to limitations in 2016 data, our model was not able to include 2016 participants in APMs other than the Shared Savings Program, the Pioneer ACO Model, and the Next Generation ACO Model.

Clinicians and groups not participating in a MIPS APM were assigned an improvement activities performance category score based on their performance in the quality and Promoting Interoperability performance categories. MIPS eligible clinicians whose 2016 PQRS data meets all the MIPS quality submission criteria (for example, submitting 6 measures with data completeness, including one outcome or high priority measures) and had an estimated Promoting Interoperability performance category score of 73 percent (if Promoting Interoperability is applicable to them) were assigned an improvement activities performance category score of 100 percent. MIPS eligible clinicians who did not participate in 2016 PQRS or the 2016 Medicare or Medicaid EHR Incentive Program (if it was applicable), received an improvement activity performance category score of 0 percent, with the rationale that these clinicians may be less likely to participate in MIPS if they have not previously participated in other programs.

For the remaining MIPS eligible clinicians not assigned an improvement activities performance category score of 0 or 100 percent in our model, we

assigned a score that corresponds to submitting one medium-weighted improvement activity. The MIPS eligible clinicians assigned an improvement activity performance category score corresponding to a medium-weighted activity include (a) those who submitted some quality measures under the 2016 PQRS but did not meet the MIPS quality submission criteria or (b) those who did not submit any quality data under the 2016 PQRS who attested under the Medicare EHR Incentive program or received an incentive payment (excluding adopt implement and upgrade payments) from the Medicaid EHR Incentive Program. We assumed that these clinicians may be likely to partially, but not fully, participate in the improvement activities category. For non-patient facing clinicians, clinicians in a small practice (consisting of 15 or fewer professionals), clinicians in practices located in a rural area, clinicians in a geographic healthcare professional shortage area (HPSA) practice or any combination thereof, the medium weighted improvement activity was assigned one-half of the total possible improvement activities performance category score (20 out of a 40 possible points or 50 percent). The remaining MIPS eligible clinicians who were not assigned an improvement activities performance category score of 0, 50, or 100 percentage points were assigned a score corresponding to one medium-weighted activity (10 out of 40 possible points or 25 percent). The policy finalized in the CY 2018 Quality Payment Program final rule at § 414.1380(b)(3), and discussed in section III.H.3.i.(1)(e)(i)(D) of this proposed rule, states that a MIPS eligible clinician or group in a practice that is certified as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, receives full credit for performance on the improvement activities performance category. In other words, MIPS eligible clinicians in a patient centered medical home or comparable specialty societies would qualify for an improvement activities performance category score of 100 percent. However, due to lack of available data, we were not able to identify MIPS eligible clinicians in patient-centered medical homes or comparable specialty societies in our scoring model.

(f) Methodology To Estimate the Complex Patient Bonus

In sections III.H.3.i.(2)(a)(ii) of this proposed rule, we are proposing to continue the complex patient bonus. Consistent with the policy to define complex patients as those with high

medical risk or with dual eligibility, our scoring model calculated the bonus by using the average Hierarchical Condition Category (HCC) risk score, as well as the MIPS eligible clinician's patients dual eligible proportion calculated for each NPI in the 2016 Physician and Other Supplier Public Use File. The dual eligible proportion for each MIPS eligible clinician was multiplied by 5. We also generated a group average HCC risk score by weighing the scores for individual clinicians in each group by the number of beneficiaries they have seen. We generated group dual eligible proportions using the weighted average dual eligible patient ratio for all MIPS eligible clinicians in the groups, which was then multiplied by 5. The complex patient bonus was calculated by adding together the average HCC risk score and the percent of dual eligible patients multiplied by 5, with a 5-point cap.

(g) Methodology To Estimate the Final Score

As proposed in sections III.H.3.h.(2)(a)(ii), III.H.3.h.(3)(a), III.H.3.h.(4)(a), III.H.3.h.(5)(d)(i) and summarized in section III.H.3.i.(2)(b) of this proposed rule, our model assigns a final score for each TIN/NPI by multiplying each performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, and adding the complex patient bonus. After adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points equal to 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for the Promoting Interoperability due to a significant hardship or other type of exception, the weight for the Promoting Interoperability performance category was redistributed to the quality performance category. For MIPS eligible clinicians who did not have a cost performance category score, the weight for the cost performance category was redistributed to the quality performance category. In our scoring model, we did not address scenarios where a zero percent weight would be assigned to the

quality performance category or the improvement activities performance category.

(h) Methodology To Estimate the MIPS Payment Adjustment

As described in section III.H.3.j.(1) of this proposed rule, we applied a hierarchy to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available (for example if a clinician qualifies for a score for an APM entity and a group score, we select the APM entity score).

We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, minimum and maximum adjustment percentages and aggregate exceptional performance payment adjustment amounts (as finalized under § 414.1405), using a performance threshold of 30 points and an exceptional performance threshold of 80 points (as proposed in sections III.H.3.j.(2) and III.H.3.j.(3) of this proposed rule). We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the Medicare Physician Fee Schedule paid amount. We considered other performance thresholds which are discussed in section VII.G. of this proposed rule.

In the CY 2017 (81 FR 77522) and CY 2018 (82 FR 53932) Quality Payment Program final rules, we applied a 90 percent participation assumption for clinicians in all practice sizes and an alternative of 80 percent participation because participation in legacy programs (PQRS, the VM, and Medicare/Medicaid EHR Incentive programs) may underestimate our expected participation in MIPS. Given the proposed changes in eligibility and the proposed opt-in policy in section VII.F.8.b. of this proposed rule, we believe that the percentage of eligible clinicians participating in MIPS will increase, so we did not apply a participation assumption.

(3) Impact of Payments by Practice Size

Using the assumptions provided above, our model estimates that \$372 million would be redistributed through budget neutrality and that the maximum positive payment adjustments are 5.6 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance.

Table 98 shows the impact of the payments by practice size and whether the clinicians submitted data to either PQRS or the Medicare or Medicaid EHR Incentive program. We continue to monitor the effects of participation, particularly for clinicians in small practices; therefore we present the summary results stratified by whether a clinician is expected to submit data to MIPS because they had submitted data to either PQRS or the Medicare or Medicaid EHR Incentive Programs, or if the clinician is facility-based. Clinicians in small practices (1–15 clinicians) that we estimate would participate in MIPS perform as well as or better than mid-size practices. Overall, clinicians in small practices participating in MIPS would receive a 1.9 percent increase in their paid amount, which is similar to the payment amount received by the total MIPS eligible clinician population. After considering the positive adjustments and subtracting the negative adjustments, eligible clinicians in small practices would have an increase in funds which is consistent with all MIPS eligible clinicians. Table 98 also shows that 96.1 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments. Among those who we estimate would not submit data to MIPS, 88 percent are in small practices (28,096 out of 31,921 clinicians). To address participation concerns, we have policies targeted towards small practices including technical assistance and special scoring policies to minimize burden and facilitate small practice participation in MIPS or APMs. Again, we plan to update these numbers in the final rule when we have actual MIPS participation for the 2017 MIPS performance period.

TABLE 98—MIPS ESTIMATED PAYMENT YEAR 2021 IMPACT ON TOTAL ESTIMATED PAID AMOUNT BY PARTICIPATION STATUS AND PRACTICE SIZE *

Practice size *	Number of MIPS eligible clinicians	Percent eligible clinicians with positive or neutral payment adjustment	Percent eligible clinicians with a positive adjustment with exceptional payment adjustment	Percent eligible clinicians with negative payment adjustment	Combined impact of negative and positive adjustments and exceptional performance payment as percent of paid amount **
Among those submitting data ***					
(1) 1–15	110,284	92.5	46.4	7.5	1.9
(2) 16–24	27,798	89.1	35.5	10.9	1.3
(3) 25–99	128,988	93.2	44.2	6.8	1.5
(4) 100+	351,174	98.8	65.3	1.2	2.5
Overall	618,244	96.1	56.2	3.9	2.0
Among those not submitting data					
(1) 1–15	28,096	0.0	0.0	100.0	–6.1
(2) 16–24	1,282	0.0	0.0	100.0	–6.0
(3) 25–99	1,871	0.0	0.0	100.0	–5.9
(4) 100+	672	0.0	0.0	100.0	–6.1
Overall	31,921	0.0	0.0	100.0	–6.1

* Practice size is the total number of TIN/NPIs in a TIN.

** 2014, 2015 and 2016 data used to estimate 2019 payment adjustments. Payments estimated using 2015 and 2016 dollars.

*** Includes facility-based clinicians whose quality data is submitted through hospital programs.

d. Potential Costs of Compliance With the Promoting Interoperability and Improvement Activities Performance Categories for Eligible Clinicians

(1) Potential Costs of Compliance With Promoting Interoperability Performance Category

In section III.H.3.h.(5)(c) of this proposed rule, we discuss the requirement to use EHR technology certified to the 2015 Edition beginning with the 2019 MIPS performance period for the Promoting Interoperability performance category. As discussed in section V.B.3 of this proposed rule, we assume a slight decrease in overall information collection burden costs for the Promoting Interoperability performance category related to having fewer measures to submit.

With respect to any costs unrelated to data submission, although this proposal would require some investment in systems updates, our policy prior to this regulation as reflected in § 414.1305, is that 2015 Edition CEHRT will be required beginning with the 2019 MIPS performance period/2021 MIPS payment year (82 FR 53671). Therefore, we do not anticipate any additional costs due to this regulation.

(2) Potential Costs of Compliance With Improvement Activities Performance Category

Under the policies established in the CY 2017 Quality Payment Program final rule, the costs for complying with the improvement activities performance category requirements could have potentially led to higher expenses for MIPS eligible clinicians. Costs per full-time equivalent primary care clinician for improvement activities will vary across practices, including for some activities or certified patient-centered medical home practices, in incremental costs per encounter, and in estimated costs per (patient) member per month.

Costs for compliance with previously finalized policies may vary based on panel size (number of patients assigned to each care team) and location of practice among other variables. For example, Magill (2015) conducted a study of certified patient-centered medical home practices in two states.⁶⁴ That study found that costs associated with a full-time equivalent primary care clinician, who was associated with certified patient-centered medical home practices, varied across practices. Specifically, the study found an average cost of \$7,691 per month in Utah

practices, and an average of \$9,658 in Colorado practices. Consequently, incremental costs per encounter were \$32.71 for certified patient-centered medical home practices in Utah and \$36.68 in Colorado (Magill, 2015). The study also found that the average estimated cost per patient member, per month, for an assumed panel of 2,000 patients was \$3.85 in Utah and \$4.83 in Colorado. However, given the lack of comprehensive historical data for improvement activities, we are unable to quantify those costs in detail at this time. The findings presented in these papers have not changed. Due to the unavailability of MIPS CY 2017 performance period data in time for this proposed rule, we do not know which improvement activities clinicians have elected. As a result, it is difficult to quantify the costs, cost savings, and benefits associated implementation of improvement activities. We will report the costs and benefits of implementing the improvement activities for the final rule if the performance data are received in time.

We have considered factors that also contribute to the difficulty of identifying compliance costs for the improvement activities performance category in the CY 2018 Quality Payment Program final rule (82 FR 53845).

⁶⁴ Magill et al. "The Cost of Sustaining a Patient-Centered Medical Home: Experience from 2 States." *Annals of Family Medicine*, 2015; 13:429–435.

Although we are unable to quantify the compliance costs of the improvement activities performance category, we do believe that because we are proposing an opt-in policy (as described in section II.C.2.c of this proposed rule), we would add approximately 87,000 additional clinicians to the MIPS eligible clinicians. In the section V.B.4 of this proposed rule, we have assumed that those who have elected to opt-in have already been voluntary reporters in MIPS and would not have additional compliance costs as a result of this regulation. Thus, we believe the overall potential cost of compliance would not increase because of this proposed rule.

Further, we anticipate that the vast majority of clinicians submitting improvement activities data to comply with existing MIPS policies could continue to submit the same activities under the policies established in this proposed rule. Previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rule-making (82 FR 54175); we are only proposing modifications to a few activities and proposing to remove one improvement activity in this proposed rule. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) and Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229) for our previously finalized 112 improvement activities established in the Improvement Activities Inventory. In section III.H.3.h.(4)(d)(ii) of this proposed rule, we are proposing 6 new improvement activities, 5 modifications and 1 removal of an existing activity.

Similarly, we believe that third parties who submit data on behalf of clinicians who prepared to submit data in the transition year will not incur additional costs as a result of this proposed rule. We request comments that provide additional information that would enable us to quantify the costs, costs savings, and benefits associated with implementation of improvement activities in the inventory.

In section III.H.3.h.(4)(e) of this proposed rule, we discuss how eligible clinicians can participate in the CMS study on burdens associated with reporting quality measures for each MIPS performance period. Eligible clinicians who are interested in participating can sign up and an adequate sample size is then selected by CMS from these potential participants. In the CY 2018 Quality Payment Program final rule, the sample size for

the CY 2018 performance period was set at a minimum of 102 MIPS eligible clinicians (81 FR 77196). Each study participant is required to complete a survey prior to submitting MIPS data and another survey after submitting MIPS data. In section III.H.3.h.(4)(e) of this proposed rule, for the CY 2019 performance period, we are proposing an increase to the sample size to a minimum of 200 MIPS eligible clinicians. However, we are proposing to make the focus group a requirement only for a selected subset of the study participants beginning with the CY 2019 performance period and future years. Thus, out of the minimum of 200 study participants as proposed above, we would select a minimum number of 100 clinicians to participate in focus groups, this selection will be done primarily by purposive sampling, and may apply random sampling only in a situation when we have to pick between same/similar participants. Completing each survey is estimated to require approximately 15 minutes; therefore, the annual hourly burden per participant is approximately 30 minutes. The annual hourly burden associated with the increase in sample size from 102 to 200 is estimated to be 49 hours (98 clinician's \times 0.5 hours). The total estimated annual cost burden is estimated to be \$10,116 (\$206.44/hour \times 49 hours). While the sample size of the study is increasing, we are not proposing a change to the sample size of MIPS eligible clinicians participating in the focus group, so no burden is estimated for participating in that activity.

e. Assumptions & Limitations

We would like to note several limitations to our estimates of MIPS eligible clinicians' eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the 2021 MIPS payment year. We based our analyses on the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on qpp.cms.gov),⁶⁵ participant lists using the APM Participation List for the third snapshot date of the 2017 QP performance period and historical PQRS data, the Medicare/Medicaid EHR Incentive Programs data, including CAHPS for PQRS, and the VM. No scoring model, including the one presented in this proposed rule, can

⁶⁵ The time period for this eligibility file (September 1, 2015 to August 31, 2016) maximizes the overlap with the performance data in our model.

fully reflect MIPS eligible clinicians' behavioral responses to MIPS because there is no substitute for actual data. The scoring model assumes that quality measures or the Medicare/Medicaid EHR Incentive Programs data submitted and the distribution of scores on those measures would be similar under the Quality Payment Program in the 2021 MIPS payment year as they were under the 2016 PQRS program. We will update results with the analysis of actual MIPS performance data if it is available in time for the publication of the final rule. The scoring model does not reflect the growth in Advanced APM participation between 2018 and 2019 (Quality Payment Program Years 2 and 3) because that data is not available at the detailed level needed for our scoring analysis.

In our MIPS eligible clinician assumptions, we assumed that 33 percent of the opt-in eligible clinicians that participated in PQRS would elect to opt-in to the MIPS program. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the proposed policy.

There are additional limitations to our estimates: (1) We only estimated the potential impact of facility-based scoring for MIPS eligible clinicians that are eligible for facility-based measurement and would have a quality performance category score of zero from failure to submit quality data; (2) because we used historic data, we assumed participation in the Promoting Interoperability and Improvement Activities performance categories would be similar to prior years in other relevant programs; (3) we assumed performance for those two categories based on population norm and not individual performance; (4) we anticipate the scores for these performance categories may differ once we receive actual MIPS performance data, and (5) to the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 98. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify in detail.

G. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been

exercised, presents rationale for our proposed policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this proposed rule, we presented the estimated impact on total allowed charges by specialty. The alternatives we considered, as discussed in the preceding preamble sections, would result in different payment rates, and therefore, result in different estimates than those shown in Table 94 (CY 2019 PFS Estimated Impact on Total Allowed Charges by Specialty).

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold and the additional performance threshold to be the critical factors affecting the distribution of payment adjustments under the Quality Payment Program, and the alternatives that we considered focus on those policies. We ran estimates with performance thresholds of 25 and 35 as an alternative to 30, so that we could estimate a more moderate increase of the performance threshold and a more aggressive increase. We also ran the models with an additional performance threshold of 70 instead of the proposed 80 points. This alternative would maintain the additional performance threshold that was in years 2 and 3. In the model with a performance threshold of 30 and an additional performance threshold of 70, we estimate that \$372 million will be redistributed through budget neutrality, and there will be a maximum payment adjustment of 4.3 percent and 8.7 percent of MIPS eligible clinicians will receive a negative payment adjustment after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In the model with a performance threshold of 25 and an additional performance threshold of 80, we estimate that \$340 million will be redistributed through budget neutrality, and there will be a maximum payment adjustment of 5.4 percent and 6.9 percent of MIPS eligible clinicians will receive a negative payment adjustment after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In the model with a performance threshold of 35 and an additional performance threshold of 80, we estimate that \$408 million will be redistributed through budget neutrality, and there will be a maximum payment adjustment of 5.8 percent and 10.9 percent of MIPS eligible clinicians will receive a negative payment adjustment after considering the MIPS payment

adjustment and the additional MIPS payment adjustment for exceptional performance.

We ran estimates on the potential change in population if we set the third low volume threshold set at 100 as an alternative to 200 covered services. We estimate that 50,260 clinicians would elect to opt-in for a total population of 658,400. We also estimated the effect of applying the opt-in policy without adding the third low-volume threshold criterion. We estimate that 19,621 clinicians would elect to opt-in for a total population of 627,761.

H. Impact on Beneficiaries

There are a number of changes in this proposed rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare providers and beneficiaries.

1. Evaluation and Management Documentation

For example, we estimate that the evaluation and management (E/M) visit documentation changes proposed in section II.I of this proposed rule may significantly reduce the amount of time practitioners spend documenting these services. While little research is available on exactly how much time physicians and non-physician practitioners spend specifically documenting E/M visits, according to one recent estimate, primary care physicians spend on average, 84 minutes or 1.4 hours per day (24 percent of the time that they spend working within an EHR) documenting progress notes.⁶⁶ Another study found that primary care physicians spend an average of 2.1 hours per day writing progress notes (both in-clinic and remote access).⁶⁷ Assuming an average of 20 patient visits per day, one E/M visit per patient, and using the higher figure of 2.1 hours per day spent documenting these visits, we estimate that documentation of an average outpatient/office E/M visit takes 6.3 minutes.⁶⁸

⁶⁶ Arndt BG, Beasley JW, Watkinson MD, et al. Tethered to the EHR: Primary care physician workload assessment using EHR event log data and time-motion observations. *Ann Fam Med*. 2017;15:427–33.

⁶⁷ Tai-Seale M, Olson CW, Li J, et al. Electronic health record logs indicate that physicians split time evenly between seeing patients and desktop medicine. *Health Aff (Millwood)*. 2017;36:655–62.

⁶⁸ 20 patient visits per day based on the average number reported in the Physicians Foundation 2016

We believe that our proposals to reduce redundancy in visit documentation, to allow auxiliary staff and the beneficiary to enter certain information in the medical record that would be verified but not required to be re-documented by the billing practitioner, to allow the choice of visit level and documentation based on MDM or time as alternatives to the current framework, and to require only minimum documentation (the amount required for a level 2 visit) for all visits except level 1 visits may reduce the documentation time by one quarter of the current time for the average office/outpatient visit. Under this assumption, these proposals would save clinicians approximately 1.6 minutes of time per office/outpatient E/M visit billed to Medicare. For a full-time practitioner whose panel of patients is 40 percent Medicare (60 percent other payers), this would translate to approximately 51 hours saved per year.⁶⁹

We note that stakeholders have emphasized to us in public comments that whatever reductions may be made to the E/M documentation guidelines for purposes of Medicare payment, physicians and non-physician practitioners will still need to document substantial information in their progress notes for clinical, legal, operational, quality reporting and other purposes, as well as potentially for other payers. Furthermore, there may be a ramp-up period for physicians and non-physician practitioners to implement the proposed documentation changes in their clinical workflow and EHR such that the effects of mitigating documentation burden may not be immediately realized. Accordingly, we believe the total amount of time practitioners spend on E/M visit documentation may remain high, despite the time savings that we estimate in this section could result from our E/M documentation proposals. These and all other improvements to payment accuracy that we are proposing for CY 2019 are described in greater detail in section II.I of this proposed rule. We welcome public comments on our assumptions for the estimated reduction in documentation burden related to these proposals.

Survey of America's Physicians, available online at https://physiciansfoundation.org/wp-content/uploads/2018/01/Biennial_Physician_Survey_2016.pdf.

⁶⁹ Forty percent of 20 total patients per day = 8 Medicare visits per day. (Eight visits per day) * (1.6 minutes per visit) * (240 days per year) = 51.2 hours.

2. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

As noted in section II.D. of this proposed rule, for CY 2019, we are aiming to increase access for Medicare beneficiaries to physicians' services that are routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology. Accordingly, we have several proposals for modernizing Medicare physician payment for communication technology-based services.

The use of communication technology-based services will provide new options for physicians to treat patients. These services could help to avoid unnecessary office visits, could consist of services that are already occurring but are not being separately paid, or could constitute new services. Medicare would pay \$14 per visit in the first year for these communication technology-based services, compared with \$92 per visit for the corresponding established patient visits.

Practitioners have a choice of when to use the communication technology-based services. Because of the low payment rate relative to that for an office visit, we are assuming that usage of these services will be relatively low. In addition, we expect that the number of new or newly billable visits and subsequent treatments will outweigh the number of times that communication technology-based services will be used instead of more costly services. As a result, we expect that the financial impact of paying for the communication technology-based services will be an increase in Medicare costs. We estimate that usage of these services will result in fewer than 1 million visits in the first year but will eventually result in more than 19 million visits per year, ultimately increasing payments under the PFS by about 0.2 percent. In order to maintain budget neutrality in setting proposed rates for CY 2019, we assumed the number of services that would result in a 0.2 percent reduction in the proposed conversion factor.

As with all estimates, and particularly those for new benefits, this outcome is highly uncertain. Because communication technology-based services is a new area for healthcare coverage, the available information on which to base estimates is limited and is usually not directly applicable, particularly to a new Medicare benefit. The cost and utilization estimates are

based on Medicare claims data together with a study published in *Health Affairs*,⁷⁰ which examined the cost and utilization of telehealth in the private sector. While this study was the most applicable for an estimate, we note that the results from this program may be different because Medicare experience may differ from private sector behavior and because the study was limited to acute respiratory infection visits. We also note that the study cites the use of direct-to-consumer telehealth companies, many of which provide access to care 24 hours per day, 7 days per week, 365 days per year, whereas the service described by HCPCS code GVC11 is limited to only established patients.

We are also proposing to make separate payment for these services when furnished by RHCs and FQHCs. A potential estimate of utilization and overall cost of these services by RHCs and FQHCs could be derived by comparing their use of chronic care management and other care management services to the same services furnished by practitioners paid under the PFS, since these care management services are also separately billable and do not take place in-person. Based on this comparison, and without considering potential variables and issues specific to these services, the impact of this proposal would be less than \$1 million in additional Medicare spending in the first year and could eventually result in up to \$20 million in spending per year in future years. These estimates are uncertain and could change after further consideration of the potential variables and issues specific to these services.

3. Outpatient Therapy Services

As noted in section II.M. of this proposed rule, we are also proposing to end functional reporting for outpatient therapy services as part of our burden reduction efforts in response to the RFI on CMS Flexibilities and Efficiencies that was issued in the CY 2018 PFS proposed rule (82 FR 34172 through 34173). Our functional reporting system currently requires therapy practitioners and providers to report, whenever functional reporting is required, non-payable HCPCS G-codes and modifiers—typically in pairs—to convey information about the beneficiary's functional limitation category and functional status throughout the PT, OT, or SLP episode of care. In addition, each time functional reporting is required on

the claim, the therapy provider must also document the functional reporting G-codes and their modifiers in the medical record. In this proposed rule, we are proposing to eliminate this requirement that therapy practitioners and providers report HCPCS G-codes and modifiers or document in the medical record to convey functional reporting status for PT, OT or SLP episode of care.

In order to quantify the amount of burden reduction, we decided to estimate the total amount of time that therapy practitioners spend doing functional reporting. To do this, we first looked at our data for CY 2017 for professional claims by the type of plan of care reported primarily by therapists in private practice (TPPs), including physical therapists, occupational therapists, and speech-language pathologists. We found that the overall utilization of the 42 functional reporting HCPCS G-codes totaled 15,456,421 single units, or 7,728,211 pairs.

We then considered the time, on average, it might take to report on the claim and document in the medical record each pair of HCPCS G-codes. We note this includes the time it takes to make the initial determination of the HCPCS G-code functional limitation category, as well as the time needed to make each initial and/or subsequent assignments for the applicable severity modifiers in order to define the patient's functional status. We then made the assumption that it would take between 1 minute and 1.5 minutes, on average, to report the HCPCS G-code and modifier pair each time functional reporting is required. Using the total utilization of G-code pairs and the range of 1 minute to 1.5 minutes, we calculated that TPPs would have saved between 128,804 and 193,206 hours (or 7,728,211 to 11,592,317 minutes) collectively in CY 2017 if the functional reporting requirements had not been in place. We believe this is a reasonable projection for the potential savings to TPPs, physicians and certain nonphysician practitioners in future years if we finalize our proposal to end functional reporting effective January 1, 2019.

Because therapy services are also furnished by providers of outpatient therapy services such as hospitals, SNFs and rehabilitation agencies that submit institutional claims, typically representing a greater amount of expenditures than practitioners submitting professional claims, we calculated additional savings for these providers using the same time assumptions of 1 to 1.5 minutes to report the HCPCS G-code and modifier

⁷⁰ Ashwood, J.S. (2017 March) Direct-To-Consumer Telehealth May Increase Access To Care But Does Not Decrease Spending. *Health Affairs*.

pair each time functional reporting is required. Our 2017 data show a total utilization of the functional reporting HCPCS G-codes is 29,053,921 single units, or 14,526,961 pairs, indicating that therapy providers would have collectively saved between 242,116 to 363,174 hours (or 14,526,961 to 21,790,442 minutes) for CY 2017 if the functional reporting requirements had not been effective during that year.

4. Physician Supervision of Diagnostic Imaging Procedures

We believe that the proposed changes to the physician supervision requirements for RAs furnishing diagnostic imaging procedures in this proposed rule as described in section II.F. of this proposed rule may significantly reduce burden for physicians. While approximately 215,000 diagnostic imaging services per year are currently performed that require personal supervision, we are not able to determine the number of these services that are performed by an RA due to limitations in the claims data. As a result, we are not able to quantify the amount of time potentially saved by physicians and practitioners under our proposal to now require direct supervision of diagnostic imaging procedures done by RAs. That said, stakeholders representing the practitioner community have indicated that changing the required supervision level for RAs will result in a redistribution of workload from radiologists to RAs, potentially resulting in improved practice efficiency and patient satisfaction. Stakeholders have stated that practitioners that utilize RAs have experienced improvements in practice efficiency, as use of RAs allows radiologists more time for professional services such as interpretation of images, and these practitioners cite greater flexibility that results in reduced wait times. Furthermore, stakeholders contend that the Medicare supervision requirements currently create disincentives to use RAs, as practitioners cannot make full use of them for Medicare patients, and this proposed change to the supervision requirement would allow RAs to be more fully utilized. For these reasons, we believe our proposal will contribute to burden reduction for physicians and practitioners providing diagnostic imaging procedures for Medicare beneficiaries.

5. Beneficiary Liability

Many proposed policy changes could result in a change in beneficiary liability as it relates to coinsurance (which is 20 percent of the fee schedule amount, if

applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in our public use file Impact on Payment for Selected Procedures available on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/>, the CY 2018 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was \$109.80, which means that in CY 2018, a beneficiary would be responsible for 20 percent of this amount, or \$21.96. Based on this proposed rule, using the CY 2019 CF, the CY 2019 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures table, is \$134.45, which means that, in CY 2019, the final beneficiary coinsurance for this service would be \$26.89.

H. Impact on Beneficiaries in the Quality Payment Program

There are several changes in this rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the Physician Fee Schedule, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new proposed measures include patient-reported outcomes, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcomes are factors frequently of interest to patients when making decisions about treatment.⁷¹ Further, the proposed policy changes in the Promoting Interoperability performance category shifts the focus to the interoperable, seamless exchange of electronic information. With the requirement that program participants use 2015 Edition CEHRT, the interoperable exchange of patient health information should be easier because the certification criteria are designed to

facilitate information exchange. In combination with the newly proposed Promoting Interoperability measure to receive and incorporate health information, beneficiaries should begin to experience improved care coordination and care transitions because clinicians have improved access to the beneficiaries' health information across the spectrum of care.

Impact on Other Health Care Programs and Providers

We estimate that CY 2019 Quality Payment Program will not have a significant economic effect on eligible clinicians and groups and believe that MIPS policies, along with increasing participation in APMs over time may succeed in improving quality and reducing costs. This may in turn result in beneficial effects on both patients and some clinicians, and we intend to continue focusing on clinician-driven, patient-centered care.

I. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's rule will be the number of reviewers of this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach in estimating the number of entities which will review this rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$107.38 per hour, including overhead and fringe benefits https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours

⁷¹ Institute of Medicine. 2013. Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis. Washington, DC: The National Academies Press. <https://doi.org/10.17226/18359>.

for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is \$859.04 (8.0 hours × \$107.38). Therefore, we estimated that the total cost of reviewing this regulation is \$5,105,275 (\$859.04 × 5,943 reviewers).

J. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Tables 98 and 99 (Accounting Statements), we have

prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2018 to CY 2019 based on the FY 2019 President's Budget baseline.

TABLE 99—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2019 Annualized Monetized Transfers From Whom To Whom?	Estimated increase in expenditures of \$0.3 billion for PFS CF update. Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 100—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2019 Annualized Monetized Transfers of beneficiary cost coinsurance. From Whom to Whom?	\$0.1 billion. Beneficiaries to Federal Government.

L. Conclusion

The proposed rule proposes to modify the consultation requirement in § 414.94(j); therefore, this analysis estimates the impact of consultations by ordering professionals. We previously estimated a total annual burden of \$275,139,000, but estimate this modification would decrease burden to an annual cost of \$122,508,675. We also estimate the broader impacts of this requirement, assuming that some ordering professionals will purchase a qualified CDSM with one-time maximum cost estimate and annual training and maintenance estimate maximum of \$394,770,600 annually for 5 years. Still, other ordering professionals who do not currently use an EHR system and are subject to this program may purchase an EHR system. For all ordering professionals subject to this program and estimated to not currently use EHR, an estimated annualized cost maximum of \$192,641,671.84 over 5 years would be incurred for all such ordering professionals to obtain an integrated qualified CDSM. We believe that in the beginning of this program, it may take longer for a Medicare beneficiary to obtain an order for an advanced diagnostic imaging service. As a result of this assumption, we have calculated an estimated impact to Medicare beneficiaries of \$68,001,000 per year with a potential offset of \$34,000,500 annually if process efficiencies are developed to integrate consultation with a qualified CDSM into the existing workflow of ordering an advanced diagnostic imaging service. This proposed rule discusses the use of

G-codes and modifiers to report AUC consultation information on claims and an alternative reporting method using a UCI. Those estimated impacts are discussed previously. We estimate the impact of transmitting such additional information on an order for an advanced diagnostic imaging service to be \$111,884,000 annually. Finally, we measure the estimated impact on furnishing professionals and facilities of the proposed expansion of the definition of applicable setting in § 414.94(b) to be the one-time update to modify billing systems at cost of \$1,740,640,000. Although the consultation and reporting requirements of this program are effective beginning January 1, 2020 with an Educational and Operations Testing Period, we attempt in this analysis to identify areas of potential qualitative benefits to both Medicare beneficiaries and the Medicare program.

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides a Regulatory Impact Analysis. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and

recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

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

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1142, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.2401 is amended in paragraph (b) by—

■ a. Revising the introductory text of the definition of “Federally qualified health center”; and

■ b. Revising the definition of “Secretary”.

The revisions read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under § 405.2434 and—

* * * * *

Secretary means the Secretary of Health and Human Services or his or her delegate.

* * * * *

■ 3. Section 405.2464 is amended by—

■ a. Revising paragraphs (a)(1), (b) heading, and (b)(1);

■ b. Redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively;

■ c. Adding a new paragraph (c); and

■ d. Revising newly redesignated paragraphs (d) and (e).

The revisions and additions read as follows:

§ 405.2464 Payment rate.

(a) *Payment rate for RHCs that are authorized to bill under the reasonable cost system.* (1) Except as specified in paragraphs (d) and (e) of this section, an RHC that is authorized to bill under the reasonable cost system is paid an all-inclusive rate that is determined by the MAC at the beginning of the cost reporting period.

* * * * *

(b) *Payment rate for FQHCs that are authorized to bill under the prospective payment system.* (1) Except as specified in paragraphs (d) and (e) of this section, a per diem rate is calculated by CMS by dividing total FQHC costs by total FQHC daily encounters to establish an average per diem cost.

* * * * *

(c) *Payment for FQHCs that are authorized to bill as grandfathered tribal FQHCs.* Grandfathered tribal FQHCs are paid at the outpatient per visit rate for Medicare as set annually by the Indian Health Service for each beneficiary visit for covered services. There are no adjustments to this rate.

(d) *Payment for care management services.* For chronic care management services furnished between January 1, 2016 and December 31, 2017, payment to RHCs and FQHCs is at the physician fee schedule national non-facility payment rate. For care management services furnished on or after January 1, 2018, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for care management services.

(e) *Payment for communication technology-based and remote evaluation services.* For communication technology-based and remote evaluation services furnished on or after January 1, 2019, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for communication technology-based and remote evaluation services.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 4. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd).

■ 5. Section 410.32 is amended by adding paragraph (b)(4) to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(4) *Supervision requirement for RRA or RPA.* Diagnostic tests that are performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, require only a direct level of physician supervision, as permitted by state law and state scope of practice regulations.

* * * * *

§ 410.59 [Amended]

■ 6. Section 410.59 is amended by removing paragraph (a)(4).

§ 410.60 [Amended]

■ 7. Section 410.60 is amended by removing paragraph (a)(4).

■ 8. Section 410.61 is amended by revising paragraph (c) to read as follows:

§ 410.61 Plan of treatment requirements for outpatient rehabilitation services.

* * * * *

(c) *Content of the plan.* The plan prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals.

* * * * *

§ 410.62 [Amended]

■ 9. Section 410.62 is amended by removing paragraph (a)(4).

■ 10. Section 410.78 is amended by—

■ a. Adding paragraphs (b)(3)(ix), (x), and (xi);

■ b. Revising paragraph (b)(4) introductory text, and

■ c. Adding paragraph (b)(4)(iv).

The additions and revision read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) * * *

(3) * * *

(ix) A renal dialysis facility (only for purposes of the home dialysis monthly ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act).

(x) The home of an individual (only for purposes of the home dialysis ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act).

(xi) A mobile stroke unit (only for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke provided in accordance with section 1834(m)(6) of the Act).

(4) Except as provided in paragraph (b)(4)(iv) of this section, originating sites must be:

* * * * *

(iv) The geographic requirements specified in paragraph (b)(4) of this section do not apply to the following telehealth services:

(A) Home dialysis monthly ESRD-related clinical assessment services furnished on or after January 1, 2019, at an originating site described in paragraph (b)(3)(vi), (ix) or (x) of this section, in accordance with section 1881(b)(3)(B) of the Act; and

(B) Services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

* * * * *

§ 410.105 [Amended]

■ 11. Section 410.105 is amended—

■ a. In paragraph (c)(1)(ii) by removing the phrase “that are consistent with the patient function reporting on the claims for services”; and

■ b. By removing paragraph (d).

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 12. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 13. Section 411.353 is amended by—
■ a. Revising paragraph (g)(1); and
■ b. Removing and reserving paragraph (g)(2).

The revision reads as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

* * * * *

(g) * * *

(1) An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the signature requirement of the exception; and

(ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant and the compensation arrangement otherwise complies with all criteria of the applicable exception.

(2) [Reserved]

■ 14. Section 411.354 is amended by adding paragraph (e) to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

* * * * *

(e) *Special rule on compensation arrangements*—(1) *Application*. This paragraph (e) applies only to compensation arrangements as defined in section 1877 of the Act and this subpart.

(2) *Writing requirement*. In the case of any requirement in this subpart for a compensation arrangement to be in writing, such requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 15. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

■ 16. Section 414.65 is amended by—
■ a. Revising paragraph (a) introductory text;
■ b. Removing paragraph (a)(1);
■ c. Redesignating paragraphs (a)(2) and (3) as paragraphs (a)(1) and (2), respectively; and
■ d. Adding paragraph (b)(3).
The revision and addition reads as follows:

§ 414.65 Payment for telehealth services.

(a) *Professional service*. The Medicare payment amount for telehealth services described under § 410.78 of this chapter is equal to the current fee schedule amount applicable for the service of the physician or practitioner, subject to paragraphs (a)(1) and (2) of this section, but must be made in accordance with the following limitations:

* * * * *

(b) * * *

(3) No originating site facility fee payment is made to an originating site described in § 410.78(b)(3)(x) or (xi) of this chapter; or to an originating site for services furnished under the exception at § 410.78(b)(4)(iv)(A) or (B) of this chapter.

* * * * *

■ 17. Section 414.94 is amended:

■ a. In paragraph (b), revising the definition of “Applicable setting”; and
■ b. Revising paragraphs (i)(3), (j), and (k) introductory text.

The revisions read as follows:

§ 414.94 Appropriate use criteria for advanced diagnostic imaging services.

* * * * *

(b) * * *

Applicable setting means a physician’s office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, an independent diagnostic testing facility, and any other provider-led outpatient setting determined appropriate by the Secretary.

* * * * *

(i) * * *

(3) Significant hardships for ordering professionals who experience any of the following:

(i) Insufficient internet access.
(ii) EHR or CDSM vendor issues.
(iii) Extreme and uncontrollable circumstances.

(j) *Consulting*. (1) Ordering Professionals and, when performed as an “incident to” service, auxiliary personnel must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system, and ordered on or after January 1, 2020.

(2) The AUC consultation specified in this paragraph (j) may be performed by auxiliary personnel (as defined in § 410.26(a)(1) of this chapter) under the direction of, and incident to, the ordering professional’s services.

(k) *Reporting*. The following information must be reported on Medicare claims for advanced diagnostic imaging services furnished in an applicable setting, paid for under an applicable payment system defined in paragraph (b) of this section, and ordered on or after January 1, 2020.

* * * * *

■ 18. Section 414.502 is amended in the definition of “Applicable laboratory” by revising paragraph (3) introductory text to read as follows:

§ 414.502 Definitions.

* * * * *

Applicable laboratory * * *

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

* * * * *

§ 414.610 [Amended]

■ 19. Section 414.610 is amended:

■ a. In paragraphs (c)(1)(ii) introductory text and (c)(5)(ii) by removing the date “December 31, 2017” and adding in its place the date “December 31, 2022”; and

■ b. By revising paragraph (c)(8).

The revision reads as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(8) *Transport of an individual with end-stage renal disease for renal dialysis services*. For ambulance services furnished during the period October 1, 2013 through September 30, 2018, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B)) furnished other than on an emergency basis by a provider of services or a renal dialysis facility, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent. For such services furnished on or after October 1, 2018, the fee schedule amount

otherwise applicable (both base rate and mileage) is reduced by 23 percent.

* * * * *

§ 414.904 [Amended]

■ 20. Section 414.904 is amended in paragraph (e)(4) by removing the phrase “acquisition cost or the applicable Medicare Part B drug payment” and adding in its place the phrase “acquisition cost or the Medicare Part B drug payment”.

■ 21. Section 414.1305 is amended by—

■ a. Revising the definition of “Ambulatory Surgical Center (ASC)-based MIPS eligible clinician”;

■ b. Adding in alphabetical order definitions for “Collection type” and “Health IT vendor”;

■ c. Revising the definitions of “High priority measure”, “Hospital-based MIPS eligible clinician”, and “Low volume threshold”;

■ d. Adding in alphabetical order a definition for “MIPS determination period”;

■ e. Revising the definitions of “MIPS eligible clinician”, “Non-patient facing MIPS eligible clinician”, “Qualified Clinical Data Registry (QCDR)”, “Qualifying APM Participant (QP)”, and “Small practice”; and

■ f. Adding in alphabetical order a definition for “Submission type”, “Submitter type”, and “Third party intermediary”.

The revisions and additions read as follows:

§ 414.1305 Definitions.

* * * * *

Ambulatory Surgical Center (ASC)-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an ambulatory surgical center setting based on claims for a period prior to the performance period as specified by CMS; and

(2) Beginning with the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS) codes used in the HIPAA standard transaction as an ambulatory surgical center setting based on claims for the MIPS determination period.

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, including, as applicable: Electronic clinical quality measures (eCQMs); MIPS Clinical Quality

Measures (MIPS CQMs), QCDR measures, Medicare Part B claims measures, the CMS Web Interface measures, the CAHPS for MIPS survey, and administrative claims measures.

* * * * *

Health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician’s CEHRT).

* * * * *

High priority measure means:

(1) For the 2019 and 2020 MIPS payment years, an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, or care coordination quality measure.

(2) Beginning with the 2021 MIPS payment year, an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure.

Hospital-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus-outpatient hospital, or emergency room setting based on claims for a period prior to the performance period as specified by CMS; and

(2) Beginning with the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period.

* * * * *

Low-volume threshold means:

(1) For the 2019 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician or group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has Medicare Part B allowed charges less than or equal to \$30,000 or provides care for 100 or fewer Medicare Part B-enrolled individuals.

(2) For the 2020 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician or group that, during the low-volume

threshold determination period described in paragraph (4) of this definition, has allowed charges for covered professional services less than or equal to \$90,000 or furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals.

(3) Beginning with the 2021 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician or group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to \$90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

(4) For the 2019 and 2020 MIPS payment years, the low-volume threshold determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding to the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the low-volume threshold determination period includes a 60-day claims run out. For the 2020 MIPS payment year, each segment of the low-volume threshold determination period includes a 30-day claims run out.

* * * * *

MIPS determination period means:

(1) Beginning with the 2021 MIPS payment year and future years, a 24-month assessment period consisting of:

(i) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out; and

(ii) A second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs.

(2) Subject to § 414.1310(b)(1)(iii), an individual eligible clinician or group that is identified as not exceeding the low-volume threshold or as a certain type of MIPS eligible clinician during the first segment of the MIPS determination period will continue to be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. An individual eligible clinician or group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of that segment.

MIPS eligible clinician as identified by a unique billing TIN and NPI combination used to assess performance, means any of the following (except as excluded under § 414.1310(b)):

(1) For the 2019 and 2020 MIPS payment years:

(i) A physician (as defined in section 1861(r) of the Act);

(ii) A physician assistant, a nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act);

(iii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); and

(iv) A group that includes such clinicians.

(2) For the 2021 MIPS payment year and future years:

(i) A clinician described in paragraph (1) of this definition;

(ii) A physical therapist or occupational therapist;

(iii) A clinical social worker (as defined in section 1861(hh)(1) of the Act);

(iv) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and

(v) A group that includes such clinicians.

* * * * *

Non-patient facing MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment year, an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the non-patient facing determination period described in paragraph (4) of this definition, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition

of a non-patient facing individual MIPS eligible clinician during the non-patient facing determination period described in paragraph (4) of this definition.

(2) Beginning with the 2021 MIPS payment year, an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician during the MIPS determination period.

(3) For purposes of this definition, a patient-facing encounter is an instance in which the individual MIPS eligible clinician or group bills for items and services furnished such as general office visits, outpatient visits, and procedure codes under the PFS, as specified by CMS.

(4) For the 2019 and 2020 MIPS payment year, the non-patient facing determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible MIPS clinician, group, or virtual group that is identified as non-patient facing during the initial 12-month segment will continue to be considered non-patient facing for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the non-patient facing determination period includes a 60-day claims run out. For the 2020 MIPS payment year and future years, each segment of the non-patient facing determination period includes a 30-day claims run out.

* * * * *

Qualified Clinical Data Registry (QCDR) means an entity with clinical expertise in medicine and quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster

improvement in the quality of care provided to patients.

* * * * *

Qualifying APM Participant (QP) means an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold under § 414.1430(a)(1), (a)(3), (b)(1), or (b)(3) for a year based on participation in an APM Entity that is also participating in an Advanced APM.

* * * * *

Small practice means:

(1) For the 2019 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians.

(2) For the 2020 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians during a 12-month assessment period that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period and includes a 30-day claims run out.

(3) Beginning with the 2021 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period.

* * * * *

Submission type means the mechanism by which the submitter type submits data to CMS, including, as applicable: Direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface.

Submitter type means the MIPS eligible clinician, group, or third party intermediary acting on behalf of a MIPS eligible clinician or group, as applicable, that submits data on measures and activities under MIPS.

Third party intermediary means an entity that has been approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and promoting interoperability performance categories.

* * * * *

■ 22. Section 414.1310 is amended by revising paragraphs (a), (b)(1)(ii) and (iii), (d), and (e)(1) and (2) to read as follows:

§ 414.1310 Applicability.

(a) *Program implementation.* Except as specified in paragraph (b) of this section, MIPS applies to payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019.

(b) * * *

(1) * * *

(ii) Is a Partial Qualifying APM Participant and does not elect to

participate in MIPS as a MIPS eligible clinician; or

(iii) Does not exceed the low-volume threshold. Beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated as MIPS eligible clinicians for the applicable payment year.

* * * * *

(d) *Clarification.* In no case will a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) apply to payments for items and services furnished during a year by a eligible clinician, including an eligible clinician described in paragraph (b) or (c) of this section, who is not a MIPS eligible clinician, including an eligible clinician who voluntarily reports on applicable measures and activities under MIPS.

(e) *Requirements for groups.* (1) Except as provided under § 414.1370(f)(2), each MIPS eligible clinician in the group will receive a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) based on the group's combined performance assessment.

(2) For individual MIPS eligible clinicians to participate in MIPS as a group, all of the following requirements must be met:

(i) Groups must meet the definition of a group at all times during the applicable performance period.

(ii) Individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN.

(iii) Individual eligible clinicians that elect to participate in MIPS as a group will have their performance assessed at the group level across all four MIPS performance categories.

(iv) Groups must adhere to an election process established by CMS, as applicable.

* * * * *

■ 23. Section 414.1315 is revised to read as follows:

§ 414.1315 Virtual groups.

(a) *Eligibility.* (1) For a MIPS payment year, a solo practitioner or a group of 10 or fewer eligible clinicians may elect to participate in MIPS as a virtual group

with at least one other such solo practitioner or group. The election must be made prior to the start of the applicable performance period and cannot be changed during the performance period. A solo practitioner or group may elect to be in no more than one virtual group for a performance period, and, in the case of a group, the election applies to all MIPS eligible clinicians in the group.

(2) Except as provided under § 414.1370(f)(2), each MIPS eligible clinician in the virtual group will receive a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) based on the virtual group's combined performance assessment.

(b) *Election deadline.* The election deadline is December 31 of the calendar year preceding the applicable performance period.

(c) *Election process.* For the 2020 MIPS payment year and future years, the virtual group election process is as follows:

(1) *Stage 1: Virtual group eligibility determination.* (i) For the 2020 MIPS payment year, the virtual group eligibility determination period is an assessment period of up to 5 months beginning on July 1 and ending as late as November 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out.

(ii) Beginning with the 2021 MIPS payment year, the virtual group eligibility determination period aligns with the first segment of the MIPS determination period, which is a 12-month assessment period beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out.

(2) *Stage 2: Virtual group formation.* (i) Solo practitioners and groups that elect to participate in MIPS as a virtual group must establish a formal written agreement that satisfies paragraph (c)(3) of this section prior to the election.

(ii) A designated virtual group representative must submit an election, on behalf of the solo practitioners and groups that compose a virtual group, to participate in MIPS as a virtual group for a performance period in a form and manner specified by CMS by the election deadline specified in paragraph (b) of this section.

(iii) The virtual group election must include each TIN and NPI associated with the virtual group and contact information for the virtual group representative.

(iv) Once an election is made, the virtual group representative must contact their designated CMS contact to update any election information that changed during a performance period at least one time prior to the start of an applicable submission period.

(3) *Virtual group agreement.* The virtual group arrangement must be set forth in a formal written agreement among the parties, consisting of each solo practitioner and group that composes a virtual group. The agreement must comply with the following requirements:

(i) Identifies each party by name, TIN, and each NPI under the TIN, and includes as parties only the solo practitioners and groups that compose the virtual group.

(ii) Is for a term of at least one performance period.

(iii) Requires each party to notify each NPI under the party's TIN regarding their participation in the MIPS as a virtual group.

(iv) Sets forth each NPI's rights and obligations in, and representation by, the virtual group, but not limited to, the reporting requirements and how participation in the MIPS as a virtual group the NPI's ability to participate in the MIPS outside of the virtual group.

(v) Describes how the opportunity to receive payment adjustments will encourage each member of the virtual group (and each NPI under each TIN in the virtual group) to adhere to quality assurance and improvement.

(vi) Requires each party to update its Medicare enrollment information, including the addition or removal of NPIs billing under its TIN, on a timely basis in accordance with Medicare program requirements and to notify the other parties of any such changes within 30 days of the change.

(vii) Requires completion of a close-out process upon termination or expiration of the agreement that requires each party to furnish all data necessary for the parties to aggregate their data across the virtual group's TINs.

(viii) Expressly requires each party to participate in the MIPS as a virtual group and comply with the requirements of the MIPS and all other applicable laws (including, but not limited to, Federal criminal law, the Federal False Claims Act, the Federal anti-kickback statute, the Federal civil monetary penalties law, the Federal physician self-referral law, and the Health Insurance Portability and Accountability Act of 1996).

(ix) Is executed on behalf of each party by an individual who is authorized to bind the party.

(d) *Virtual group reporting requirements.* For solo practitioners and groups of 10 or fewer eligible clinicians to participate in MIPS as a virtual group, all of the following requirements must be met:

(1) Virtual groups must meet the definition of a virtual group at all times during the applicable performance period.

(2) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs.

(3) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group will have their performance assessed at the virtual group level across all four MIPS performance categories.

(4) Virtual groups must adhere to the election process described in paragraph (c) of this section.

■ 24. Section 414.1320 is amended by revising paragraphs (b)(2) and (c)(2) and adding paragraphs (d) and (e) to read as follows:

§ 414.1320 MIPS performance period.

* * * * *

(b) * * *

(2) Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2018, up to and including the full CY 2018 (January 1, 2018 through December 31, 2018).

(c) * * *

(2) Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2019, up to and including the full CY 2019 (January 1, 2019 through December 31, 2019).

(d) Beginning with the 2022 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year.

(2) The improvement activities performance categories is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(e) For purposes of the 2022 MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

■ 25. Section 414.1325 is revised to read as follows:

§ 414.1325 Data submission requirements.

(a) *Applicable performance categories.* (1) Except as provided in paragraph (a)(2) of this section or under § 414.1370, as applicable, individual MIPS eligible clinicians and groups must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance with this section. Except for the Medicare Part B claims submission type, the data may also be submitted on behalf of the individual MIPS eligible clinician or group by a third party intermediary described at § 414.1400.

(2) There are no data submission requirements for:

(i) The cost performance category or administrative claims-based quality measures. Performance in the cost performance category and on such measures is calculated by CMS using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period.

(ii) The quality or cost performance category, as applicable, for MIPS eligible clinicians and groups that are scored under the facility-based measurement scoring methodology described in § 414.1380(e).

(b) *Data submission types for individual MIPS eligible clinicians.* An individual MIPS eligible clinician may submit their MIPS data using:

(1) For the quality performance category, the direct, login and upload, and Medicare Part B claims (for small practices only beginning with the 2021 MIPS payment year) submission types.

(2) For the improvement activities or Promoting Interoperability performance categories, the direct, login and upload, or login and attest submission types.

(c) *Data submission types for groups.* Groups may submit their MIPS data using:

(1) For the quality performance category, the direct, login and upload, Medicare Part B claims (for small practices only beginning with the 2021 MIPS payment year), and CMS Web Interface (for groups consisting of 25 or more eligible clinicians or a third party intermediary submitting on behalf of a group) submission types.

(2) For the improvement activities or Promoting Interoperability performance categories, the direct, login and upload, or login and attest submission types.

(d) *Use of multiple data submission types.* Beginning with the 2021 MIPS payment year, MIPS eligible clinicians, groups, and virtual groups may submit their MIPS data using multiple data submission types for any performance category described in paragraph (a)(1) of this section, as applicable; provided, however, that the MIPS eligible clinician, group, or virtual group uses the same identifier for all performance categories and all data submissions.

(e) *Data submission deadlines.* The data submission deadlines are as follows:

(1) For the direct, login and upload, login and attest, and CMS Web Interface submission types, March 31 following the close of the applicable performance period or a later date as specified by CMS.

(2) For the Medicare Part B claims submission type, data must be submitted on claims with dates of service during the applicable performance period that must be processed no later than 60 days following the close of the applicable performance period.

■ 26. Section 414.1330 is revised to read as follows:

§ 414.1330 Quality performance category.

(a) For a MIPS payment year, CMS uses the following quality measures, as applicable, to assess performance in the quality performance category:

(1) Measures included in the MIPS final list of quality measures established by CMS through rulemaking;

(2) QCDR measures approved by CMS under § 414.1400;

(3) Facility-based measures described in § 414.1380; and

(4) MIPS APM measures described in § 414.1370.

(b) Unless a different scoring weight is assigned by CMS, performance in the quality performance category comprises:

(1) 60 percent of a MIPS eligible clinician's final score for MIPS payment year 2019.

(2) 50 percent of a MIPS eligible clinician's final score for MIPS payment year 2020.

(3) 45 percent of a MIPS eligible clinician's final score for MIPS payment year 2021.

■ 27. Section 414.1335 is amended by revising paragraphs (a)(1), (2), and (3) to read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) * * *

(1) *For Medicare Part B claims measures, MIPS CQMs, eCQMs, or QCDR measures.* (i) Subject to paragraph (a)(1)(ii) of this section,

submit data on at least six measures including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician or group, report on each measure that is applicable.

(ii) MIPS eligible clinicians and groups that report on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician or group, report on each measure that is applicable.

(2) *For CMS Web Interface measures.* (i) Report on all measures included in the CMS Web Interface. The group must report on the first 248 consecutively ranked beneficiaries in the sample for each measure or module.

(ii) If the sample of eligible assigned beneficiaries is less than 248, then the group must report on 100 percent of assigned beneficiaries.

(iii) The group is required to report on at least one measure for which there is Medicare patient data.

(3) *For the CAHPS for MIPS survey.* (i) For the 12-month performance period, a group that wishes to voluntarily elect to participate in the CAHPS for MIPS survey must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measures data to CMS.

(ii) [Reserved]

* * * * *

■ 28. Section 414.1340 is amended by revising paragraphs (a) introductory text, (b) introductory text, and (c) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or the eCQMs must submit data on:

* * * * *

(b) MIPS eligible clinicians and groups submitting quality measure data on the Medicare Part B claims measures must submit data on:

* * * * *

(c) Groups submitting quality measures data on CMS Web Interface measures or the CAHPS for MIPS survey, must meet the data submission requirement on the sample of the Medicare Part B patients CMS provides.

■ 29. Section 414.1350 is revised to read as follows:

§ 414.1350 Cost performance category.

(a) *Specification of cost measures.* For purposes of assessing performance of MIPS eligible clinicians on the cost performance category, CMS specifies cost measures for a performance period.

(b) *Attribution.* (1) Cost measures are attributed at the TIN/NPI level.

(2) For the total per capita cost measure, beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter.

(3) For the Medicare Spending per Beneficiary (MSPB) measure, an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period.

(4) For the acute condition episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills at least 30 percent of inpatient evaluation and management (E&M) visits during the trigger event for the episode.

(5) For the procedural episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills a Medicare Part B claim with a trigger code during the trigger event for the episode.

(6) For the acute inpatient medical condition episode-based measures specified beginning with the 2019 performance period, an episode is attributed to each MIPS eligible clinician who bills inpatient E&M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization.

(7) For the procedural episode-based measures specified beginning with the 2019 performance period, an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCP/CS/CPT procedure codes.

(c) *Case minimums.* (1) For the total per capita cost measure, the case minimum is 20.

(2) For the Medicare spending per beneficiary measure, the case minimum is 35.

(3) For the episode-based measures specified for the 2017 performance period, the case minimum is 20.

(4) For the procedural episode-based measures specified beginning with the 2019 performance period, the case minimum is 10.

(5) For the acute inpatient medical condition episode-based measures specified beginning with the 2019 performance period, the case minimum is 20.

(d) *Scoring weight.* Unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the cost performance category comprises:

(1) Zero percent of a MIPS eligible clinician's final score for MIPS payment year 2019.

(2) 10 percent of a MIPS eligible clinician's final score for MIPS payment year 2020.

(3) 15 percent of a MIPS eligible clinician's final score for MIPS payment year 2021.

■ 30. Section 414.1355 is amended by revising paragraphs (a), (b) introductory text, and (c) to read as follows:

§ 414.1355 Improvement activities performance category.

(a) For a MIPS payment year, CMS uses improvement activities included in the MIPS final inventory of improvement activities established by CMS through rulemaking to assess performance in the improvement activities performance category.

(b) Unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the improvement activities performance category comprises:

* * * * *

(c) The following are the list of subcategories, of which, with the exception of Participation in an APM, include activities for selection by a MIPS eligible clinician or group:

(1) Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.

(2) Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a QCDR.

(3) Care coordination, such as timely communication of test results, timely exchange of clinical information to patients or other clinicians, and use of remote monitoring or telehealth.

(4) Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision making mechanisms.

(5) Patient safety and practice assessment, such as through the use of clinical or surgical checklists and practice assessments related to maintaining certification.

(6) Participation in an APM.

(7) Achieving health equity, such as for MIPS eligible clinicians that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, people living in rural areas, and people in geographic HPSAs.

(8) Emergency preparedness and response, such as measuring MIPS eligible clinician participation in the Medical Reserve Corps, measuring registration in the Emergency System for Advance Registration of Volunteer Health Professionals, measuring relevant reserve and active duty uniformed services MIPS eligible clinician activities, and measuring MIPS eligible clinician volunteer participation in domestic or international humanitarian medical relief work.

(9) Integrated behavioral and mental health, such as measuring or evaluating such practices as: Co-location of behavioral health and primary care services; shared/integrated behavioral health and primary care records; cross training of MIPS eligible clinicians, and integrating behavioral health with primary care to address substance use disorders or other behavioral health conditions, as well as integrating mental health with primary care.

■ 31. Section 414.1360 is amended by revising paragraph (a)(1) to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) * * *

(1) *Via direct, login and upload, and login and attest.* For the applicable performance period, submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

* * * * *

§ 414.1365 [Removed]

■ 32. Section 414.1365 is removed.

■ 33. Section 414.1370 is amended by revising paragraphs (b)(3), (f)(2), (g)(4), (h)(4) heading, (h)(5)(i)(A) and (B), and (h)(5)(ii) introductory text to read as follows:

§ 414.1370 APM scoring standard under MIPS.

* * * * *

(b) * * *

(3) The APM bases payment on quality measures and cost/utilization; and

* * * * *

(f) * * *

(2) MIPS eligible clinicians who participate in a group or have elected to

participate in a virtual group and who are also on a MIPS APM Participation List will be included in the assessment under MIPS for purposes of producing a group or virtual group score and under the APM scoring standard for purposes of producing an APM Entity score. The MIPS payment adjustment for these eligible clinicians is based solely on their APM Entity score; if the APM Entity group is exempt from MIPS all eligible clinicians within that APM Entity group are also exempt from MIPS.

(g) * * *

(4) *Promoting Interoperability (PI).* (i) For the 2019 and 2020 MIPS payment years, each Shared Savings Program ACO participant TIN must report data on the Promoting Interoperability performance category separately from the ACO, as specified in § 414.1375(b)(2). The ACO participant TIN scores are weighted according to the number of MIPS eligible clinicians in each TIN as a proportion of the total number of MIPS eligible clinicians in the APM Entity group, and then aggregated to determine an APM Entity score for the ACI performance category.

(ii) For the 2019 and 2020 MIPS payment years, for APM Entities in MIPS APMs other than the Shared Savings Program, CMS uses one score for each MIPS eligible clinician in the APM Entity group to derive a single average APM Entity score for the Promoting Interoperability performance category. Beginning with the 2021 MIPS payment year, for APM Entities in MIPS APMs including the Shared Savings Program, CMS uses one score for each MIPS eligible clinician in the APM Entity group to derive a single average APM Entity score for the Promoting Interoperability performance category. The score for each MIPS eligible clinician is the higher of either:

(A) A group score based on the measure data for the Promoting Interoperability performance category reported by a TIN for the MIPS eligible clinician according to MIPS submission and reporting requirements for groups; or

(B) An individual score based on the measure data for the Promoting Interoperability performance category reported by the MIPS eligible clinician according to MIPS submission and reporting requirements for individuals.

(iii) In the event that a MIPS eligible clinician participating in a MIPS APM receives an exception from the Promoting Interoperability performance category reporting requirements, such eligible clinician will be assigned a null score when CMS calculates the APM Entity's Promoting Interoperability

performance category score under the APM scoring standard.

(A) If all MIPS eligible clinicians in an APM Entity have been excepted from reporting the Promoting Interoperability performance category, the performance category weight will be reweighted to zero for the APM Entity for that MIPS performance period.

(B) [Reserved]

(h) * * *

(4) *Promoting Interoperability.* * * *

(5) * * *

(i) * * *

(A) In 2017, the improvement activities performance category is reweighted to 25 percent and the Promoting Interoperability performance category is reweighted to 75 percent; and

(B) Beginning in 2018, the Promoting Interoperability performance category is reweighted to 75 percent and the improvement activities performance category is reweighted to 25 percent.

(ii) If CMS reweights the Promoting Interoperability performance category to zero percent:

* * * * *

■ 34. Section 414.1375 is amended by—
■ a. Revising the section heading, paragraphs (a), (b) introductory text, and (b)(2); and

■ b. Removing paragraph (b)(3).

The revisions and addition read as follows:

§ 414.1375 Promoting Interoperability (PI) performance category.

(a) *Final score.* Unless a different scoring weight is assigned by CMS under sections 1848(o)(2)(D), 1848(q)(5)(E)(ii), or 1848(q)(5)(F) of the Act, performance in the Promoting Interoperability performance category comprises 25 percent of a MIPS eligible clinician's final score for each MIPS payment year.

(b) *Reporting for the Promoting Interoperability performance category.* To earn a performance category score for the Promoting Interoperability performance category for inclusion in the final score, a MIPS eligible clinician must:

* * * * *

(2) *Report MIPS—Promoting Interoperability objectives and measures.* Report on the objectives and associated measures as specified by CMS for the Promoting Interoperability performance category for the performance period as follows:

(i) For the 2019 and 2020 MIPS payment years: For each base score measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or claim an exclusion for each measure

that includes an option for an exclusion; and

(ii) Beginning with the 2021 MIPS payment year:

(A) Report that the MIPS eligible clinician completed the actions included in the Security Risk Analysis measure during the year in which the performance period occurs; and

(B) For each required measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or an exclusion for each measure that includes an option for an exclusion.

■ 35. Section 414.1380 is revised to read as follows:

§ 414.1380 Scoring.

(a) *General.* MIPS eligible clinicians are scored under MIPS based on their performance on measures and activities in four performance categories. MIPS eligible clinicians are scored against performance standards for each performance category and receive a final score, composed of their performance category scores, and calculated according to the final score methodology.

(1) *Performance standards.* (i) For the quality performance category, measures are scored between zero and 10 measure achievement points. Performance is measured against benchmarks. Measure bonus points are available for submitting high-priority measures, submitting measures using end-to-end electronic reporting, and in small practices that submit data on at least 1 quality measure. Beginning with the 2020 MIPS payment year, improvement scoring is available in the quality performance category.

(ii) For the cost performance category, measures are scored between 1 and 10 points. Performance is measured against a benchmark. Starting with the 2024 MIPS payment year, improvement scoring is available in the cost performance category.

(iii) For the improvement activities performance category, each improvement activity is assigned a certain number of points. The points for all submitted activities are summed and scored against a total potential performance category score of 40 points.

(iv) For the Promoting Interoperability performance category, each measure is scored against a maximum number of points. The points for all submitted measures are summed and scored against a total potential performance category score of 100 points.

(2) [Reserved]

(b) *Performance categories.* MIPS eligible clinicians are scored under MIPS in four performance categories.

(1) *Quality performance category*—(i) *Measure achievement points.* For the 2019, 2020, and 2021 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340. The number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

(A) *Lack of benchmark or case minimum.* (1) Except as provided in paragraph (b)(1)(i)(A)(2) of this section, for the 2019, 2020, and 2021 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

(2) The following measures are excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points:

(i) Each submitted CMS Web Interface-based measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement, or is redesignated as pay-for-reporting for all Shared Savings Program accountable care organizations by the Shared Savings Program; and

(ii) Each administrative claims-based measure that does not have a benchmark or meet the case minimum requirement.

(B) *Lack of complete data.* (1) Except as provided in paragraph (b)(1)(i)(B)(2) of this section, for each submitted

measure that does not meet the data completeness requirement:

(i) For the 2019 MIPS payment year, MIPS eligible clinicians receive 3 measure achievement points;

(ii) For the 2020 and 2021 MIPS payment years, MIPS eligible clinicians other than small practices receive 1 measure achievement point, and small practices receive 3 measure achievement points; and

(iii) Beginning with the 2022 MIPS payment year, MIPS eligible clinicians other than small practices receive zero measure achievement points, and small practices receive 3 measure achievement points.

(2) MIPS eligible clinicians receive zero measure achievement points for each submitted CMS Web Interface-based measure that does not meet the data completeness requirement.

(ii) *Benchmarks.* Benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

(A) Each benchmark must have a minimum of 20 individual clinicians or groups who reported the measure meeting the case minimum requirement at paragraph (b)(1)(iii) of this section and the data completeness requirement at § 414.1340 and having a performance rate that is greater than zero.

(B) CMS Web Interface collection type uses benchmarks from the corresponding reporting year of the Shared Savings Program.

(iii) *Minimum case requirements.* Except for the all-cause hospital readmission measure, the minimum case requirement is 20 cases. For the all-cause hospital readmission measure, the minimum case requirement is 200 cases.

(iv) *Topped out measures.* CMS will identify topped out measures in the benchmarks published for each Quality Payment Program year.

(A) For the 2020 MIPS payment year, each topped out measure specified by CMS through rulemaking receives no more than 7 measure achievement points, provided that the benchmark for the applicable collection type is identified as topped out in the benchmarks published for the 2018 MIPS performance period.

(B) Beginning with the 2021 MIPS payment year, each measure (except for measures in the CMS Web Interface) for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years receives no more than 7 measure achievement points in the second consecutive year it is identified as topped out, and beyond.

(v) *Measure bonus points.* MIPS eligible clinicians receive measure bonus points for the following measures, except as otherwise required under § 414.1335, regardless of whether the measure is included in the MIPS eligible clinician's total measure achievement points.

(A) *High priority measures.* Subject to paragraph (b)(1)(v)(A)(1) of this section, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures.

(1) *Limitations.* (i) Each high priority measure must have a benchmark at paragraph (b)(1)(ii) of this section, meet the case minimum requirement at (b)(1)(iii) of this section, meet the data completeness requirement at § 414.1340, and have a performance rate that is greater than zero.

(ii) For the 2019, 2020, and 2021 MIPS payment years, the total measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points.

(iii) Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that collect data in accordance with § 414.1325 on a single measure via multiple collection types receive measure bonus points only once.

(B) *End-to-end electronic reporting.* Subject to paragraph (b)(1)(v)(B)(1) of this section, MIPS eligible clinicians receive 1 measure bonus point for each measure (except claims-based measures) submitted with end-to-end electronic reporting for a quality measure under certain criteria determined by the Secretary.

(1) *Limitations.* (i) For the 2019, 2020, and 2021 MIPS payment years, the total measure bonus points for measures submitted with end-to-end electronic reporting cannot exceed 10 percent of the total available measure achievement points.

(ii) Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that collect data in accordance with § 414.1325 on a single measure via multiple collection types receive measure bonus points only once.

(C) *Small practices.* Beginning with the 2021 MIPS payment year, MIPS eligible clinicians in small practices receive 3 measure bonus points if they submit data to MIPS on at least 1 quality measure.

(vi) *Improvement scoring.* Improvement scoring is available to MIPS eligible clinicians that

demonstrate improvement in performance in the current MIPS performance period compared to performance in the performance period immediately prior to the current MIPS performance period based on measure achievement points.

(A) Improvement scoring is available when the data sufficiency standard is met, which means when data are available and a MIPS eligible clinician has a quality performance category achievement percent score for the previous performance period and the current performance period.

(1) Data must be comparable to meet the requirement of data sufficiency which means that the quality performance category achievement percent score is available for the current performance period and the previous performance period and quality performance category achievement percent scores can be compared.

(2) Quality performance category achievement percent scores are comparable when submissions are received from the same identifier for two consecutive performance periods.

(3) If the identifier is not the same for 2 consecutive performance periods, then for individual submissions, the comparable quality performance category achievement percent score is the highest available quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for the individual. For group, virtual group, and APM Entity submissions, the comparable quality performance category achievement percent score is the average of the quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for each of the individuals in the group.

(4) Improvement scoring is not available for clinicians who were scored under facility-based measurement in the performance period immediately prior to the current MIPS performance period.

(B) The improvement percent score may not total more than 10 percentage points.

(C) The improvement percent score is assessed at the performance category level for the quality performance category and included in the calculation of the quality performance category percent score as described in paragraph (b)(1)(vii) of this section.

(1) The improvement percent score is awarded based on the rate of increase in the quality performance category achievement percent score of MIPS eligible clinicians from the previous

performance period to the current performance period.

(2) An improvement percent score is calculated by dividing the increase in the quality performance category achievement percent score from the prior performance period to the current performance period by the prior performance period quality performance category achievement percent score multiplied by 10 percent.

(3) An improvement percent score cannot be lower than zero percentage points.

(4) For the 2020 and 2021 MIPS payment year, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

(5) The improvement percent score is zero if the MIPS eligible clinician did not fully participate in the quality performance category for the current performance period.

(D) For the purpose of improvement scoring methodology, the term "quality performance category achievement percent score" means the total measure achievement points divided by the total available measure achievement points, without consideration of measure bonus points or improvement percent score.

(E) For the purpose of improvement scoring methodology, the term "improvement percent score" means the score that represents improvement for the purposes of calculating the quality performance category percent score as described in paragraph (b)(1)(vii) of this section.

(F) For the purpose of improvement scoring methodology, the term "fully participate" means the MIPS eligible clinician met all requirements in §§ 414.1335 and 414.1340.

(vii) *Quality performance category score.* A MIPS eligible clinician's quality performance category percent score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) of this section. The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) of this section is added to that result. The quality performance category percent score cannot exceed 100 percentage points.

(A) Beginning with the 2021 MIPS payment year, for MIPS eligible clinicians that submit data on a measure significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety

concerns, the total available measure achievement points category are reduced by 10 points.

(B) Beginning with the 2021 MIPS payment year, for groups that register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements, the total available measure achievement points are reduced by 10 points.

(viii) *ICD-10 updates.* Beginning with the 2018 MIPS performance period, measures significantly impacted by ICD-10 updates, as determined by CMS, will be assessed based only on the first 9 months of the 12-month performance period. For purposes of this paragraph (b)(1)(viii), CMS will make a determination as to whether a measure is significantly impacted by ICD-10 coding changes during the performance period. CMS will publish on the CMS website which measures require a 9-month assessment process by October 1st of the performance period if technically feasible, but by no later than the beginning of the data submission period at § 414.1325(f)(1).

(2) *Cost performance category.* For each cost measure attributed to a MIPS eligible clinician, the clinician receives one to ten achievement points based on the clinician's performance on the measure during the performance period compared to the measure's benchmark. Achievement points are awarded based on which benchmark decile range the MIPS eligible clinician's performance on the measure is between. CMS assigns partial points based on the percentile distribution.

(i) Cost measure benchmarks are determined by CMS based on cost measure performance during the performance period. At least 20 MIPS eligible clinicians or groups must meet the minimum case volume specified under § 414.1350(c) for a cost measure in order for a benchmark to be determined for the measure. If a benchmark is not determined for a cost measure, the measure will not be scored.

(ii) A MIPS eligible clinician must meet the minimum case volume specified under § 414.1350(c) to be scored on a cost measure.

(iii) The cost performance category percent score is the sum of the following, not to exceed 100 percent:

(A) The total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points; and

(B) The cost improvement score, as determined under paragraph (b)(2)(iv) of this section.

(iv) The cost improvement score is determined for a MIPS eligible clinician

that demonstrates improvement in performance in the current MIPS performance period compared to their performance in the immediately preceding MIPS performance period.

(A) The cost improvement score is determined at the measure level for the cost performance category.

(B) The cost improvement score is calculated only when data sufficient to measure improvement is available. Sufficient data is available when a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the same cost measure(s) for 2 consecutive performance periods. If the cost improvement score cannot be calculated because sufficient data is not available, then the cost improvement score is zero.

(C) The cost improvement score is determined by comparing the number of measures with a statistically significant change (improvement or decline) in performance; a change is determined to be significant based on application of a t-test. The number of cost measures with a significant decline is subtracted from the number of cost measures with a significant improvement, with the result divided by the number of cost measures for which the MIPS eligible clinician or group was scored for 2 consecutive performance periods. The resulting fraction is then multiplied by the maximum cost improvement score.

(D) The cost improvement score cannot be lower than zero percentage points.

(E) The maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points.

(v) A cost performance category percent score is not calculated if a MIPS eligible clinician or group is not attributed any cost measures for the performance period because the clinician or group has not met the minimum case volume specified by CMS for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the clinician or group.

(3) *Improvement activities performance category.* Subject to paragraphs (b)(3)(i) and (ii) of this section, the improvement activities performance category score equals the total points for all submitted improvement activities divided by 40 points, multiplied by 100 percent. MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 10 points for each medium-

weighted improvement activity and 20 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325.

(i) For MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent.

(ii) For MIPS eligible clinicians in a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, the improvement activities performance category score is 100 percent. For the 2019 MIPS payment year, at least one practice site within a group's TIN must be certified or recognized as a patient-centered medical home or comparable specialty practice. For the 2020 MIPS payment year and future years, at least 50 percent of the practice sites within a group's TIN must be recognized as a patient-centered medical home or comparable specialty practice. MIPS eligible clinicians that wish to claim this status for purposes of receiving full credit in the improvement activities performance category must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive this credit. A practice is certified or recognized as a patient-centered medical home if it meets any of the following criteria:

(A) The practice has received accreditation from one of four accreditation organizations that are nationally recognized;

(1) The Accreditation Association for Ambulatory Health Care;

(2) The National Committee for Quality Assurance (NCQA);

(3) The Joint Commission; or

(4) The Utilization Review Accreditation Commission (URAC).

(B) The practice is participating in a Medicaid Medical Home Model or Medical Home Model.

(C) The practice is a comparable specialty practice that has received the NCQA Patient-Centered Specialty Recognition.

(D) The practice has received accreditation from other certifying bodies that have certified a large number of medical organizations and meet national guidelines, as determined by the Secretary. The Secretary must

determine that these certifying bodies must have 500 or more certified member practices, and require practices to include the following:

- (1) Have a personal physician/clinician in a team-based practice.
- (2) Have a whole-person orientation.
- (3) Provide coordination or integrated care.
- (4) Focus on quality and safety.
- (5) Provide enhanced access.

(4) *Promoting Interoperability performance category.* (i) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the base score, performance score, and any applicable bonus scores, not to exceed 100 percentage points. A MIPS eligible clinician cannot earn a performance score or bonus score unless they have earned a base score.

(A) A MIPS eligible clinician earns a base score by reporting for each base score measure, as applicable: The numerator (of at least one) and denominator, or a yes/no statement, or an exclusion.

(B) A MIPS eligible clinician earns a performance score by reporting on the

performance score measures specified by CMS. A MIPS eligible clinician may earn up to 10 or 20 percentage points as specified by CMS for each performance score measure reported.

(C) A MIPS eligible clinician may earn the following bonus scores:

(1) A bonus score of 5 percentage points for reporting to one or more additional public health agencies or clinical data registries.

(2) A bonus score of 10 percentage points for attesting to completing one or more improvement activities specified by CMS using CEHRT.

(3) For the 2020 MIPS payment year, a bonus score of 10 percentage points for submitting data for the measures for the base score and the performance score generated solely from CEHRT as defined in § 414.1305 for 2019 and subsequent years.

(ii) For the 2021 MIPS payment year, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the scores for each of the required 6 measures and any applicable bonus scores, not to exceed 100 points.

(A) A MIPS eligible clinician earns a score for each measure by reporting, as applicable: The numerator (of at least one) and denominator, or a yes/no statement, or an exclusion.

(B) A MIPS eligible clinician may earn a bonus score of 5 points each for two optional measures.

(iii) Beginning with the 2022 MIPS payment year, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the scores for each of the required 8 measures, not to exceed 100 points.

(A) A MIPS eligible clinician earns a score for each measure by reporting, as applicable: The numerator (of at least one) and denominator, or a yes/no statement, or an exclusion.

(B) [Reserved]

(c) *Final score calculation.* Each MIPS eligible clinician receives a final score of 0 to 100 points for a performance period for a MIPS payment year calculated as follows. If a MIPS eligible clinician is scored on fewer than 2 performance categories, he or she receives a final score equal to the performance threshold.

For the 2019 MIPS payment year:

Final score = [(quality performance category percent score × quality performance category weight) + (cost performance category percent score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)], not to exceed 100 points.

For the 2020 MIPS payment year:

Final score = [(quality performance category percent score × quality performance category weight) + (cost performance category percent score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + [the complex patient bonus + the small practice bonus], not to exceed 100 points.

Beginning with the 2021 MIPS payment year:

Final score = [(quality performance category percent score × quality performance category weight) + (cost performance category percent score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + the complex patient bonus, not to exceed 100 points.

(1) *Performance category weights.* The weights of the performance categories in the final score are as follows, unless a different scoring weight is assigned under paragraph (c)(2) of this section:

- (i) Quality performance category weight is defined under § 414.1330(b).
- (ii) Cost performance category weight is defined under § 414.1350(d).
- (iii) Improvement activities performance category weight is defined under § 414.1355(b).
- (iv) Promoting Interoperability performance category weight is defined under § 414.1375(a).

(2) *Reweight the performance categories.* (i) In accordance with paragraph (c)(2)(ii) of this section, a scoring weight different from the weights specified in paragraph (c)(1) of this section will be assigned to a

performance category, and its weight as specified in paragraph (c)(1) of this section will be redistributed to another performance category or categories, in the following circumstances:

(A) CMS determines based on the following circumstances that there are not sufficient measures and activities applicable and available under section 1848(q)(5)(F) of the Act.

(1) For the quality performance category, CMS cannot calculate a score for the MIPS eligible clinician because there is not at least one quality measure applicable and available to the clinician.

(2) For the cost performance category, CMS cannot reliably calculate a score for the cost measures that adequately captures and reflects the performance of the MIPS eligible clinician.

(3) Beginning with the 2021 MIPS payment year, for the quality, cost, improvement activities, and Promoting Interoperability performance categories, the MIPS eligible clinician joins an existing practice during the final 3 months of the performance period year that is not participating in MIPS as a group or joins a practice that is newly formed during the final 3 months of the performance period year.

(4) For the Promoting Interoperability performance category beginning with the 2021 MIPS payment year, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical social worker, or clinical psychologist. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in

paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(5) For the Promoting Interoperability performance category for the 2019, 2020, and 2021 MIPS payment years, the MIPS eligible clinician is a nurse practitioner, physician assistant, clinical nurse specialist, or certified registered nurse anesthetist. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(6) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, the MIPS eligible clinician demonstrates through an application submitted to CMS that they were subject to extreme and uncontrollable circumstances that prevented the clinician from collecting information that the clinician would submit for a performance category or submitting information that would be used to score a performance category for an extended period of time. Beginning with the 2021 MIPS payment year, in the event that a MIPS eligible clinician submits data for the quality, cost, or improvement activities performance categories, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(7) For the 2019 MIPS payment year, for the quality and improvement activities performance categories, the MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS. In the event that a MIPS eligible clinician submits data for a performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(8) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, the MIPS eligible clinician

was located in an area affected by extreme and uncontrollable circumstances as identified by CMS. In the event that a MIPS eligible clinician submits data for the quality or improvement activities performance categories, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(B) Under section 1848(q)(5)(E)(ii) of the Act, CMS estimates that the proportion of MIPS eligible clinicians who are physicians as defined in section 1861(r) of the Act and earn a Promoting Interoperability performance category score of at least 75 percent is 75 percent or greater. The estimation is based on data from the performance period that occurs four years before the MIPS payment year and does not include physicians for whom the Promoting Interoperability performance category is weighted at zero percent.

(C) Under section 1848(o)(2)(D) of the Act, a significant hardship exception or other type of exception is granted to a MIPS eligible clinician based on the following circumstances for the Promoting Interoperability performance category. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(1) The MIPS eligible clinician demonstrates through an application submitted to CMS that they lacked sufficient internet access during the performance period, and insurmountable barriers prevented the clinician from obtaining sufficient internet access.

(2) The MIPS eligible clinician demonstrates through an application submitted to CMS that they were subject to extreme and uncontrollable circumstances that caused their CEHRT to be unavailable.

(3) The MIPS eligible clinician was located in an area affected by extreme

and uncontrollable circumstances as identified by CMS.

(4) The MIPS eligible clinician demonstrates through an application submitted to CMS that 50 percent or more of their outpatient encounters occurred in practice locations where they had no control over the availability of CEHRT.

(5) The MIPS eligible clinician is a non-patient facing MIPS eligible clinician as defined in § 414.1305.

(6) The MIPS eligible clinician is a hospital-based MIPS eligible clinician as defined in § 414.1305.

(7) The MIPS eligible clinician is an ASC-based MIPS eligible clinician as defined in § 414.1305.

(8) Beginning with the 2020 MIPS payment year, the MIPS eligible clinician demonstrates through an application submitted to CMS that their CEHRT was decertified either during the performance period for the MIPS payment year or during the calendar year preceding the performance period for the MIPS payment year, and the MIPS eligible clinician made a good faith effort to adopt and implement another CEHRT in advance of the performance period. In no case may a MIPS eligible clinician be granted this exception for more than 5 years.

(9) Beginning with the 2020 MIPS payment year, the MIPS eligible clinician demonstrates through an application submitted to CMS that they are in a small practice as defined in § 414.1305, and overwhelming barriers prevent them from complying with the requirements for the Promoting Interoperability performance category.

(ii) A scoring weight different from the weights specified in paragraph (c)(1) of this section will be assigned to a performance category, and its weight as specified in paragraph (c)(1) of this section will be redistributed to another performance category or categories, as follows:

(A) For the 2019 MIPS payment year:

Performance category	Weighting for the 2019 MIPS payment year (%)	Reweight scenario if no promoting interoperability performance category score (%)	Reweight scenario if no quality performance category percent score (%)	Reweight scenario if no improvement activities performance category score (%)
Quality	60	85	0	75
Cost	0	0	0	0
Improvement Activities	15	15	50	0
Promoting Interoperability	25	0	50	25

(B) For the 2020 MIPS payment year:

Reweight scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
—Scores for all four performance categories	50	10	15	25
Reweight One Performance Category:				
—No Cost	60	0	15	25
—No Promoting Interoperability	75	10	15	0
—No Quality	0	10	45	45
—No Improvement Activities	65	10	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	10	90	0
—No Promoting Interoperability and no Improvement Activities	90	10	0	0
—No Quality and no Improvement Activities	0	10	0	90

(C) For the 2021 MIPS payment year:

Reweight scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
—Scores for all four performance categories	45	15	15	25
Reweight One Performance Category:				
—No Cost	60	0	15	25
—No Promoting Interoperability	70	15	15	0
—No Quality	0	15	40	45
—No Improvement Activities	60	15	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	15	85	0
—No Promoting Interoperability and no Improvement Activities	85	15	0	0
—No Quality and no Improvement Activities	0	15	0	85

(iii) For MIPS eligible clinicians submitting data as a group or virtual group, in order for the Promoting Interoperability performance category to be reweighted in accordance with paragraph (c)(2)(ii) of this section, all of the MIPS eligible clinicians in the group must qualify for reweighting based on the circumstances described in paragraph (c)(2)(i) of this section.

(3) *Complex patient bonus.* For the 2020 and 2021 MIPS payment years, provided that a MIPS eligible clinician, group, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as follows:

(i) For MIPS eligible clinicians and groups, the complex patient bonus is calculated as follows: [The average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by

clinicians in a group] + [the dual eligible ratio × 5].

(ii) For APM entities and virtual groups, the complex patient bonus is calculated as follows: [The beneficiary weighted average HCC risk score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively] + [the average dual eligible ratio for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or virtual group, respectively, × 5].

(iii) The complex patient bonus cannot exceed 5.0.

(4) *Small practice bonus.* A small practice bonus of 5 points will be added to the final score for the 2020 MIPS payment year for MIPS eligible clinicians, groups, virtual groups, and APM Entities that meet the definition of a small practice as defined at § 414.1305 and participate in MIPS by submitting data on at least one performance

category in the 2018 MIPS performance period.

(d) *Scoring for APM Entities.* MIPS eligible clinicians in APM Entities that are subject to the APM scoring standard are scored using the methodology under § 414.1370.

(e) *Scoring for facility-based measurement.* For the payment in 2021 MIPS payment year and subsequent years and subject to paragraph (e)(6)(vi) of this section, a MIPS eligible clinician or group may be scored under the quality and cost performance categories using facility-based measures under the methodology described in this paragraph (e).

(1) *General.* The facility-based measurement scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified as meeting the requirements in paragraph (e)(2) of this section.

(i) The measures for facility-based measurement consist of the measure set finalized for the fiscal year VBP program for which payment begins during the applicable MIPS performance period.

(ii) Beginning with the 2021 MIPS payment year, the scoring methodology

applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period.

(2) *Eligibility for facility-based measurement.* MIPS eligible clinicians are eligible for facility-based measurement for a MIPS payment year if they are determined to be facility-based as an individual clinician or as part of a group, as follows:

(i) *Facility-based individual determination.* A MIPS eligible clinician is facility-based if the clinician meets all of the following criteria:

(A) Furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting based on claims for a 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the performance period with a 30-day claims run out.

(B) Furnishes at least 1 covered professional service in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, or emergency room setting.

(C) Can be attributed, under the methodology specified in paragraph (e)(5) of this section, to a facility with a VBP score for the applicable period.

(ii) *Facility-based group determination.* A facility-based group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements under paragraph (e)(2)(i) of this section.

(3) [Reserved]

(4) *Data submission for facility-based measurement.* There are no data submission requirements for individual clinicians scored under facility-based measurement. A group must submit data in the improvement activities or Promoting Interoperability performance categories in order to be scored as a facility-based group.

(5) *Determination of applicable facility score.* (i) A facility-based clinician is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the clinician provided services to the most Medicare beneficiaries during the year the claims are drawn from in paragraph (e)(2) of this section. If there is an equal number of Medicare beneficiaries treated at

more than one facility, the value-based purchasing score for the highest scoring facility is used.

(ii) A facility-based group is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under paragraph (e)(5)(i) of this section.

(6) *MIPS performance category scoring under the facility-based measurement scoring standard—(i) Measures.* The quality and cost measures are those adopted under the value-based purchasing program of the facility for the year described in paragraph (e)(1)(i) of this section.

(ii) *Benchmarks.* The benchmarks are those adopted under the value-based purchasing program of the facility program for the year described in paragraph (e)(1)(i) of this section.

(iii) *Performance period.* The performance period for facility-based measurement is the performance period for the measures adopted under the value-based purchasing program of the facility program for the year described in paragraph (e)(1)(i) of this section.

(iv) *Quality.* The quality performance category percent score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1)(i) of this section and awarding a score associated with that same percentile performance in the MIPS quality performance category percent score for those MIPS-eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. This score will not include a consideration of improvement in the MIPS quality performance category score.

(v) *Cost.* The cost performance category percent score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1)(i) of this section and awarding a score associated with that same percentile performance in the MIPS cost performance category percent score for those MIPS eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. This score will not include a consideration of improvement in cost measures.

(A) *Other cost measures.* MIPS eligible clinicians who are scored under facility-based measurement are not scored on cost measures described in paragraph (b)(2) of this section.

(B) [Reserved]

(vi) *Use of score from facility-based measurement.* The MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology described in paragraph (e)(6) of this section unless a clinician or group receive a higher combined MIPS quality and cost performance category scores through another MIPS submission.

■ 36. Section 414.1395 is amended by revising paragraphs (b) and (c) to read as follows:

§ 414.1395 Public reporting.

* * * * *

(b) *Maintain existing public reporting standards.* With the exception of data that must be mandatorily reported on Physician Compare, for each program year, CMS relies on established public reporting standards to guide the information available for inclusion on Physician Compare. The public reporting standards require data included on Physician Compare to be statistically valid, reliable, and accurate; comparable across collection types; and meet the reliability threshold. And, to be included on the public facing profile pages, the data must also resonate with website users, as determined by CMS.

(c) *First year measures.* For each program year, CMS does not publicly report any first year measure for the first 2 years, meaning any measure in its first 2 years of use in the quality and cost performance categories. After the first 2 years, CMS reevaluates measures to determine when and if they are suitable for public reporting.

* * * * *

■ 37. Section 414.1400 is revised to read as follows:

§ 414.1400 Third party intermediaries.

(a) *General.* (1) MIPS data may be submitted on behalf of a MIPS eligible clinician, group, or virtual group by any of the following third party intermediaries:

- (i) A QCDR;
- (ii) A qualified registry;
- (iii) A health IT vendor; or
- (iv) A CMS-approved survey vendor.

(2) QCDRs, qualified registries, and health IT vendors may submit MIPS data for any of the following MIPS performance categories:

- (i) Quality, except for data on the CAHPS for MIPS survey;
- (ii) Improvement activities; or
- (iii) Promoting Interoperability, if the MIPS eligible clinician, group, or virtual group is using CEHRT.

(3) CMS-approved survey vendors may submit data on the CAHPS for MIPS survey for the MIPS quality performance category.

(4) To be approved as a third party intermediary, an entity must agree to meet the applicable requirements of this section, including, but not limited to, the following:

(i) A third party intermediary's principle place of business and retention of any data must be based in the U.S.

(ii) If the data is derived from CEHRT, a QCDR, qualified registry, or health IT vendor must be able to indicate its data source.

(iii) All data must be submitted in the form and manner specified by CMS.

(5) All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Such certification must be made in a form and manner and at such time as specified by CMS.

(b) *QCDR approval criteria*—(1) *QCDR self-nomination*. For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a QCDR must self-nominate September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a QCDR must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a QCDR for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing QCDRs that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period.

(2) *Establishment of a QCDR entity*. (i) Beginning with the 2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(ii) If the entity uses an external organization for purposes of data collection, calculation, or transmission, it must have a signed, written agreement with the external organization that specifically details the responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period.

(3) *QCDR measures for the quality performance category*. (i) For purposes

of QCDRs submitting data for the MIPS quality performance category, CMS considers the following types of quality measures to be QCDR measures:

(A) Measures that are not included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year; and

(B) Measures that are included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year, but have undergone substantive changes, as determined by CMS.

(ii) For the 2020 MIPS payment year and future years, an entity seeking to become a QCDR must submit specifications for each measure, activity, and objective that the entity intends to submit to for MIPS (including the information described in paragraphs (b)(3)(ii)(A) and (B) of this section) at the time of self-nomination. In addition, no later than 15 calendar days following CMS approval of any QCDR measure specifications, the entity must publicly post the measure specifications for each QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted.

(A) For QCDR measures, the entity must submit the measure specifications for each QCDR measure, including: Name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms.

(B) For MIPS quality measures, the entity must submit the MIPS measure IDs and specialty-specific measure sets, as applicable.

(C) Beginning with the 2021 MIPS payment year, as a condition of a QCDR measure's approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year.

(iii) A QCDR must include the CMS-assigned QCDR measure ID when submitting data on any QCDR measure to CMS.

(c) *Qualified registry approval criteria*—(1) *Qualified registry self-nomination*. For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a qualified registry must self-nominate from September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a

qualified registry must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a qualified registry for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period.

(2) *Establishment of a qualified registry entity*. Beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(d) *Health IT vendor approval criteria*. Health IT vendors must meet the criteria specified at § 414.1400(a)(4).

(e) *CMS-approved survey vendor approval criteria*. Entities seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. The application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. For an entity to be a CMS-approved survey vendor, it must meet the following criteria:

(1) The entity must have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

(i) At least 3 years of experience administering mixed-mode surveys (that is, surveys that employ multiple modes to collect data), including mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);

(ii) At least 3 years of experience administering surveys to a Medicare population;

(iii) At least 3 years of experience administering CAHPS surveys within the past 5 years;

(iv) Experience administering surveys in English and one of the following languages: Cantonese, Korean, Mandarin, Russian, or Vietnamese;

(v) Use equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers,

collect data via CATI, electronically administer the survey and schedule callbacks to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and

(vi) Employ a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

(2) The entity has certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data.

(3) The entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors.

(4) The entity has submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts.

(5) The entity has agreed to participate and cooperate, and has required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors.

(6) The entity has sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

(f) *Remedial action and termination of third party intermediaries.* (1) If CMS determines that a third party intermediary (that is, a QCDR, health IT vendor, qualified registry, or CMS approved survey vendor) has ceased to meet one or more of the applicable criteria for approval, or has submitted data that is inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

(i) Require the third party intermediary to submit a corrective action plan (CAP) to CMS to address the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring. The CAP must be submitted to CMS by a date specified by CMS.

(ii) If the third party intermediary has a data error rate of 3 percent or more, publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

(2) CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible

clinician, group, or virtual group for one or more of the following reasons:

(i) CMS has grounds to impose remedial action;

(ii) CMS has not received a CAP within the specified time period or the CAP is not accepted by CMS; and

(iii) The third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.

(3) For purposes of paragraph (e) of this section, CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if the submitted data:

(i) Includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and

(ii) Affects more than three percent (but less than five percent) of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary.

■ 38. Section 414.1405 is amended by—

■ a. Adding paragraphs (b)(6) and (d)(5);

■ b. Revising paragraph (e) and;

■ c. Adding paragraphs (f) and (g).

The additions and revision read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(6) The performance threshold for the 2021 MIPS payment year is 30 points.

* * * * *

(d) * * *

(5) The additional performance threshold for the 2021 MIPS payment year is 80 points.

(e) *Application of adjustments to payments.* Except as specified in paragraph (f) of this section, in the case of covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by a MIPS eligible clinician during a MIPS payment year beginning with 2019, the amount otherwise paid under Part B with respect to such covered professional services and MIPS eligible clinician for such year, is multiplied by 1, plus the sum of the MIPS payment adjustment factor divided by 100, and as applicable, the additional MIPS payment adjustment factor divided by 100.

(f) *Exception to application of MIPS payment adjustment factors to model-specific payments under Section 1115A APMs.* The payment adjustment factors specified under paragraph (e) of this section are not applicable to payments:

(1) Made only to participants in a model tested under section 1115A of the Act;

(2) That would otherwise be subject to the requirement to apply the MIPS payment adjustment factors if the

payment is made with respect to a MIPS eligible clinician to participating in a section 1115A model; and

(3) Are model-specific payments that have a specified payment amount; or use a methodology for calculating a model-specific payment that is paid in a consistent manner to participants to which application of the MIPS payment adjustment factors would potentially interfere with CMS's ability to effectively evaluate the impact of the APM.

■ 39. Section 414.1415 is amended by revising paragraphs (a)(1)(i), (b)(1) through (3), (c) introductory text, (c)(3)(i)(A), and (c)(6) to read as follows:

§ 414.1415 Advanced APM criteria.

(a) * * *

(1) * * *

(i) Require at least 50 percent, or for QP Performance Periods beginning in 2019, 75 percent of eligible clinicians in each participating APM Entity group, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers; or

* * * * *

(b) * * *

(1) To be an Advanced APM, an APM must include quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM.

(2) At least one of the quality measures used in the payment arrangement as specified in paragraph (c)(1) of this section must:

(i) For QP Performance Periods before January 1, 2020, have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(A) Used in the MIPS quality performance category, as described in § 414.1330;

(B) Endorsed by a consensus-based entity;

(C) Developed under section 1848(s) of the Act;

(D) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(E) Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid; and

(ii) For QP Performance Periods beginning on or after January 1, 2020, be:

(A) Finalized on the MIPS final list of measures, as described in § 414.1330;

(B) Endorsed by a consensus-based entity; or

(C) Determined by CMS to be evidenced-based, reliable, and valid.

(3) In addition to the quality measure described under paragraph (b)(2) of this section, the quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must include at least one additional measure that is an outcome measure unless CMS determines that there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period. Beginning January 1, 2020, the included outcome measure must satisfy the criteria in paragraph (b)(2) of this section.

(c) *Financial risk.* To be an Advanced APM, except as described in paragraph (c)(6) of this section, an APM must either meet the financial risk standard under paragraph (c)(1) or (2) of this section and the nominal amount standard under paragraph (c)(3) or (4) of this section or be an expanded Medical Home Model under section 1115A(c) of the Act.

* * * * *

(3) * * *

(i) * * *

(A) For QP Performance Periods beginning in 2017, through 2024, 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities; or

* * * * *

(6) *Capitation.* A full capitation arrangement meets this Advanced APM criterion. For purposes of this part, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. Arrangements between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 U.S.C. 422) are not considered capitation arrangements for purposes of this paragraph (c)(6).

* * * * *

■ 40. Section 414.1420 is amended by revising paragraphs (b), (c)(2) and (3), (d) introductory text, (d)(3)(i), and (d)(7) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(b) *Use of CEHRT.* To be an Other Payer Advanced APM, CEHRT must be used by at least 50 percent, or for QP Performance Periods on or after January 1, 2020, 75 percent of participants in

each participating APM Entity group, or each hospital if hospitals are the APM Entities, in the other payer arrangement to document and communicate clinical care.

(c) * * *

(2) At least one of the quality measures used in the payment arrangement as specified in paragraph (c)(1) of this section must:

(i) For QP Performance Period before January 1, 2020, have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(A) Used in the MIPS quality performance category, as described in § 414.1330;

(B) Endorsed by a consensus-based entity;

(C) Developed under section 1848(s) of the Act;

(D) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(E) Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid; and

(ii) For QP Performance Periods beginning on or after January 1, 2020, be:

(A) Finalized on the MIPS final list of measures, as described in § 414.1330;

(B) Endorsed by a consensus-based entity; or

(C) Determined by CMS to be evidenced-based, reliable, and valid.

(3) To meet the quality measure use criterion under paragraph (c)(1) of this section, a payment arrangement must:

(i) For QP Performance Periods before January 1, 2020, use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. This criterion also applies for payment arrangements determined to be Other Payer Advanced APMs on or before January 1, 2020, but only for the Other Payer Advanced APM determination made with respect to the arrangement for the CY 2020 QP Performance Period (regardless of whether that determination is a single- or multi-year determination).

(ii) For QP Performance Periods on or after January 1, 2020, in addition to the quality measure described under paragraph (c)(2) of this section, use at least one additional measure that is an outcome measure and meets the criteria in paragraph (c)(2)(ii) of this section if there is such an applicable outcome measure on the MIPS quality measure list.

(d) *Financial risk.* To be an Other Payer Advanced APM, except as described in paragraph (d)(7) of this section, a payment arrangement must meet either the financial risk standard

under paragraph (d)(1) or (2) of this section and the nominal amount standard under paragraph (d)(3) or (4) of this section, or be a Medicaid Medical Home Model with criteria comparable to an expanded Medical Home Model under section 1115A(c) of the Act.

* * * * *

(3) * * *

(i) For QP Performance Periods 2019 through 2024, 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement if financial risk is expressly defined in terms of revenue; or, 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

* * * * *

(7) *Capitation.* A full capitation arrangement meets this Other Payer Advanced APM criterion. For purposes of paragraph (d)(3) of this section, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the payment arrangement for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed for the purpose of reconciling or sharing losses incurred or savings earned by the participant. Arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 U.S.C. 422) are not considered capitation arrangements for purposes of this paragraph (c)(7).

* * * * *

■ 41. Section 414.1440 is amended by revising paragraphs (d)(1) through (3) to read as follows:

§ 414.1440 Qualifying APM participant determination: All-payer combination option.

* * * * *

(d) * * *

(1) CMS performs QP determinations following the QP Performance Period using payment amount and/or patient count information submitted from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31. CMS will use data for the same time periods for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. CMS will use the payment amount or patient count method, applying the more advantageous of the two for both the Medicare and other payer portions of the Threshold score calculation, regardless of the method used for the Medicare Threshold Score calculation.

(2) An APM Entity may request that CMS make QP determinations at the APM Entity level, an eligible clinician may request that CMS make QP determinations at the eligible clinician level, and an eligible clinician or an APM Entity may request that CMS makes QP determinations at the TIN-level in instances where all clinicians who reassigned billing rights to the TIN are participating in a single APM Entity. CMS makes QP determinations at either the APM Entity, eligible clinician, or TIN level. Eligible clinicians assessed at the eligible clinician level under the Medicare Option at § 414.1425(b)(2) will be assessed at the eligible clinician level only under the All-Payer Combination Option. Eligible Clinicians may meet the Medicare and the All-Payer Combination Option thresholds using the payment amount method for both thresholds, the patient account method for both thresholds, or the payment amount method for one threshold and the patient account method for the other threshold.

(3) CMS uses data at the same level for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. When QP determinations are made at the eligible clinician or, at the TIN level when all clinicians who have reassigned billing rights to the TIN are included in a single APM Entity; and if the Medicare Threshold score for the APM Entity group is higher than when calculated for the eligible clinician or TIN, CMS makes QP determinations using a weighted Medicare Threshold Score that is factored into an All-Payer Combination Option Threshold Score.

* * * * *

■ 42. Section 414.1445 is amended by revising paragraph (b)(1) and adding paragraphs (c)(2)(i) and (ii) to read as follows:

§ 414.1445 Determination of other payer advanced APMs.

* * * * *

(b) * * *

(1) *Payer initiated Other Payer Advanced APM determination process.* Beginning in 2018, and each year thereafter, at a time determined by CMS a payer with a Medicare Health Plan payment arrangement may request, in a form and manner specified by CMS, that CMS determine whether a Medicare Health Plan payment arrangement meets the Other Payer Advanced APM criteria set forth in § 414.1420. A payer with a Medicare Health Plan payment arrangement must submit its requests by the annual Medicare Advantage bid

deadline of the year prior to the relevant QP Performance Period.

* * * * *

(c) * * *

(2) * * *

(i) Based on the submission by an eligible clinician or payer of evidence that CMS determines sufficiently demonstrates that CEHRT is used as specified in § 414.1420(b) by participants in the payment arrangement, CMS will consider the CEHRT criterion in § 414.1420(b) is satisfied for that payment arrangement.

(ii) [Reserved]

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 43. The authority citation for part 415 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 44. Section 415.172 is amended by revising paragraph (b) to read as follows:

§ 415.172 Physician fee schedule payment for services of teaching physicians.

* * * * *

(b) *Documentation.* Except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by a physician, resident, or nurse.

* * * * *

■ 45. Section 415.174 is amended—

■ a. In paragraph (a)(3)(iii) by adding

“and” at the end of the paragraph;

■ b. In paragraph (a)(3)(iv) by removing

“; and” and adding a period in its place;

■ c. By removing paragraph (a)(3)(v); and

■ d. By adding paragraph (a)(6).

The addition reads as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

(a) * * *

(6) The medical records must document the extent of the teaching physician's participation in the review and direction of services furnished to

each beneficiary. The extent of the teaching physician's participation may be demonstrated by the notes in the medical records made by a physician, resident, or nurse.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 46. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 47. Section 495.4 is amended in the definition of “EHR reporting period” by adding reserved paragraph (1)(iv) and adding paragraph (1)(v) to read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period. * * *

(1) * * *

(iv) [Reserved]

(v) Under the Medicaid Promoting Interoperability Program, for the CY 2021 payment year:

(A) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2021 that ends before October 31, 2021, or that ends before an earlier date in CY 2021 that is specified by the state and approved by CMS in the State Medicaid HIT plan described at § 495.332.

(B) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2021 that ends before October 31, 2021, or that ends before an earlier date in CY 2021 that is specified by the state and approved by CMS in the State Medicaid HIT plan described at § 495.332.

* * * * *

■ 48. Section 495.24 is amended by revising paragraphs (d)(6)(i)(B) and (d)(8)(i)(B)(2), to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * * *

(d) * * *

(6) * * *

(i) * * *

(B) *Measures.* In accordance with paragraph (a)(2) of this section, an EP must satisfy 2 out of the 3 following measures in paragraphs (d)(6)(i)(B)(1) through (3) of this section except those measures for which an EP qualifies for an exclusion under paragraph (a)(3) of this section.

(1) During the EHR reporting period, more than 5 percent of all unique

patients (or their authorized representatives) seen by the EP actively engage with the electronic health record made accessible by the provider and do either of the following:

(i) View, download or transmit to a third party their health information;

(ii) Access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or

(iii) A combination of paragraphs (d)(6)(i)(B)(1)(i) and (ii) of this section.

(2) A secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient, for more than 5 percent of all unique patients seen by the EP during the EHR reporting period.

(3) Patient generated health data or data from a nonclinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP during the EHR reporting period.

* * * * *

(8) * * *

(i) * * *

(B) * * *

(2) *Syndromic surveillance reporting.*

The EP is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting, or from any other setting from which ambulatory syndromic surveillance data are collected by the state or a local public health agency.

* * * * *

■ 49. Section 495.332 is amended by adding paragraphs (f)(3), (4), and (5) to read as follows:

§ 495.332 State Medicaid health information technology (HIT) plan requirements.

* * * * *

(f) * * *

(3) An alternative date within CY 2021 by which all "EHR reporting periods" (as defined under § 495.4) for the CY 2021 payment year for Medicaid EPs demonstrating they are meaningful EHR users must end. The alternative date selected by the state must be earlier than October 31, 2021, and must not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state.

(4) An alternative date within CY 2021 by which all clinical quality measure reporting periods for the CY 2021 payment year for Medicaid EPs demonstrating they are meaningful EHR users must end. The alternative date selected by the state must be earlier than October 31, 2021, and must not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state.

(5) For the CY 2019 payment year and beyond, a state-specific listing of which clinical quality measures selected by CMS are considered to be high priority measures for purposes of Medicaid EP clinical quality measure reporting.

* * * * *

Dated: June 22, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Note: The following appendices will not appear in the Code of Federal Regulations.

BILLING CODE 4120-01-P

APPENDIX 1: PROPOSED MIPS QUALITY MEASURES

NOTE: Except as otherwise proposed herein, previously finalized measures and specialty measure sets will continue to apply for the 2021 MIPS payment year and future years.

In this proposed rule, we are proposing to adopt 10 new quality measures into the MIPS Program for the 2021 MIPS payment year and future years. These measures are discussed in detail below.

TABLE Group A: Proposed New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years

A.1. Continuity of Pharmacotherapy for Opioid Use Disorder

Category	Description
NQF #:	N/A
Quality #:	TBD
Description:	Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment
Measure Steward:	University of Southern California
Numerator:	Adults in the denominator who have at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than seven days.
Denominator:	Adults aged 18 years and older who had a diagnosis of OUD.
Exclusions:	Pharmacotherapy for OUD initiated after June 30th of performance period
Measure Type:	Process
Measure Domain:	Effective Clinical Care
High Priority Measure:	Yes (Appropriate Use and Opioid-Related)
Collection Type:	MIPS CQMs Specifications
Rationale:	<p>We are proposing to adopt this measure because the opioid epidemic is immensely affecting the nation and it is imperative to measure opioid use. This clinical concept is currently not represented within MIPS. There are three existing opioid use related measures for MIPS but none cover the topic of pharmacotherapy. This measure captures patients diagnosed with opioid use disorder (OUD) who are receiving and adhering to the prescribed therapy. The performance data provided by the measure steward supports there is opportunity for improvement. Based on the measure steward research, only about a quarter to a third of individuals with commercial insurance or Medicaid coverage taking medication for OUD remained on the medication for at least 180 days without a gap of more than seven days. The MAP acknowledged the public health importance of measures that address opioid use disorder and noted the gap in this area. However, the MAP recognized that the current measure is specified and tested at the health plan and state level and recommended the measure be refined and resubmitted prior to rulemaking because the measure has not been tested or endorsed at the clinician or clinician group level. While we agree that the measure should be tested at the clinician level, we believe there is an urgent need for measures that address the opioid epidemic affecting the nation. We believe that the health plan level version of the measure can be adapted to the clinician level by revising the measure analytics to assess the proportion of patients with opioid use disorder that achieve continuity of pharmacotherapy aggregated at the clinician level.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at the following link: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>

A.2. Average Change in Functional Status Following Lumbar Spine Fusion Surgery

Category	Description
NQF #:	2643
Quality #:	TBD
Description:	For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative functional status to one year (nine to fifteen months) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	<p>The average change (preoperative to one year post-operative) in functional status for all patients in the denominator.</p> <p>There is not a traditional numerator for this measure; the measure calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative ODI score.</p> <p>The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose function decreases post-operatively. Example below:</p> <p>Patient Pre-op ODI :I Post-op ODI :I Change in ODI Patient A: I 47 :I 18 :I 29 Patient B: I 45 :I 52 :I -7 Patient C: I 56 :I 12 :I 44 Patient D: I 62 :I 25 :I 37 Patient E: I 42 :I 57 :I -15 Patient F: I 51 :I 10 :I 41 Patient G: I 62 :I 25 :I 37 Patient H: I 43 :I 20 :I 23 Patient I: I 74 :I 35 :I 39 Patient J: I 59 :I 23 :I 36 Average change in ODI one year post-op 26.4 points on a 100 point scale</p>
Denominator:	<p>Eligible Population: Patients with lumbar spine fusion procedures (Arthrodesis Value Set) occurring during a 12 month period for patients age 18 and older at the start of that period.</p> <p>Denominator: Patients within the eligible population whose functional status was measured by the Oswestry Disability Index, version 2.1a (ODI, v2.1a) within three months preoperatively AND at one year (+/- 3 months) postoperatively.</p> <p>*The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed</p>
Exclusions:	<p>The following exclusions must be applied to the eligible population: Patient had cancer (Spine Cancer Value Set), fracture (Spine Fracture Value Set) or infection (Spine Infection Value Set) related to the spine. Patient had idiopathic or congenital scoliosis (Congenital Scoliosis Value Set)</p>
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	<p>We are proposing to adopt this measure because it measures an important patient reported outcome evaluating the functional status change from pre- to post-operative. Results of the measure can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP supported this measure for rulemaking and recognized that improvement in functional status is an important outcome to patients and was encouraged by the potential addition of more patient-reported outcome measures to the MIPS set.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at the following link: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>

A.3. Average Change in Functional Status Following Total Knee Replacement Surgery

Category	Description
NQF #:	2653
Quality #:	TBD
Description:	For patients age 18 and older undergoing total knee replacement surgery, the average change from pre-operative functional status to one year (nine to fifteen months) post-operative functional status using the Oxford Knee Score (OKS) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	<p>There is not a traditional numerator for this measure; the measure is calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative OKS score.</p> <p>For example: The average change in knee function was an increase of 15.9 points one year post-operatively on a 48 point scale.</p> <p>The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account patients who have an improvement and patients whose function decreases post-operatively. Example below:</p> <p>Patient Pre-op OKS :I Postop OKS :I Change in OKS Patient A: I 33 :I 45 :I 12 Patient B: I 17 :I 39 :I 22 Patient C: I 16 :I 31 :I 15 Patient D: I 23 :I 40 :I 17 Patient E: I 34 :I 42 :I 8 Patient F: I 10 :I 42 :I 32 Patient G: I 14 :I 44 :I 30 Patient H: I 32 :I 44 :I 12 Patient I: I 19 :I 45 :I 26 Patient J: I 26 :I 19 :I -7 Patient K: I 24 :I 43 :I 19 Patient L: I 29 :I 34 :I 5 Patient M : I 23 :I 39 :I 16 Patient N: I 29 :I 45 :I 16 Patient O: I 29 :I 45 :I 16 Patient P: I 34 :I 41 :I 7 Patient Q: I 11 :I 14 :I 3 Patient R: I 13 :I 39 :I 26 Patient S: I 18 :I 45 :I 27 Average change in OKS one year post-op 15.9 points on a 48 point scale</p>
Denominator:	<p>Eligible Population: Patients with total knee replacement procedures (Primary TKR Value Set, Revision TKR Value Set) occurring during a 12 month period for patients age 18 and older at the start of that period.</p> <p>Denominator: Patients within the eligible population whose functional status was measured by the Oxford Knee Score within three months preoperatively AND at one year (+/- 3 months) postoperatively</p> <p>*The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed</p>
Exclusions:	None
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	<p>We are proposing to adopt this measure because it measures an important patient reported outcome evaluating the functional status change from pre- to post-operative. Results can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP supported this measure for rulemaking and recognized that improvement in functional status is an important outcome to patients and was encouraged by the potential addition of more patient-reported outcome measures to the MIPS set.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at the following link: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>

A.4. Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	TBD
Description:	For patients age 18 and older undergoing lumbar discectomy laminotomy surgery, the average change from pre-operative functional status to three months (6 to 20 weeks) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	<p>The average change (preoperative to three months post-operative) in functional status for all patients in the denominator.</p> <p>There is not a traditional numerator for this measure; the measure is calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative ODI score.</p> <p>The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose function decreases post-operatively. Example below:</p> <p>Patient Pre-op ODI :I Post-op ODI :I Change in ODI Patient A: I 47 :I 18 :I 29 Patient B: I 45 :I 52 :I -7 Patient C: I 56 :I 12 :I 44 Patient D: I 62 :I 25 :I 37 Patient E: I 42 :I 57 :I -15 Patient F: I 51 :I 10 :I 41 Patient G: I 62 :I 25 :I 37 Patient H: I 43 :I 20 :I 23 Patient I: I 74 :I 35 :I 39 Patient J: I 59 :I 23 :I 36 Average change in ODI three months post-op 26.4 points on a 100 point scale</p>
Denominator:	<p>Eligible Population: Patients with lumbar discectomy laminotomy procedure (Single Disc-Lami Value Set) for a diagnosis of disc herniation (Disc Herniation Value Set)) occurring during a 12 month period for patients age 18 and older at the start of that period.</p> <p>Denominator: Patients within the eligible population whose functional status was measured by the Oswestry Disability Index, version 2.1a (ODI, v2.1a) within three months preoperatively AND at three months (6 to 20 weeks) postoperatively.</p> <p>*The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed</p>
Exclusions:	The following exclusions must be applied to the eligible population: Patient had any additional spine procedures performed on the same date as the lumbar discectomy laminotomy.
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	<p>We are proposing to adopt this measure because it measures an important patient reported outcome evaluating the functional status change from pre- to post-operative. The results of the measure can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at the following link: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>

A.5. Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	TBD
Description:	Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Female patients who received an order for at least one DXA scan in the measurement period.
Denominator:	Female patients ages 50 to 64 years with an encounter during the measurement period.
Exclusions:	<p>Exclude from the denominator patients with a combination of risk factors (as determined by age) or one of the independent risk factors:</p> <ul style="list-style-type: none"> • Ages: 50-54 (>=4 combo risk factors) or 1 independent risk factor • Ages: 55-59 (>=3 combo risk factors) or 1 independent risk factor • Ages: 60-64 (>=2 combo risk factors) or 1 independent risk factor <p>Combination risk factors (The following risk factors are all combination risk factors; they are grouped by when they occur in relation to the measurement period):</p> <p>The following risk factors may occur any time in the patient's history but must be active during the measurement period:</p> <ul style="list-style-type: none"> • White (race) • BMI <= 20 kg/m2 (must be the first BMI of the measurement period) • Smoker (current during the measurement period) • Alcohol consumption (> two units per day (one unit is 12 oz. of beer, 4 oz. of wine, or 1 oz. of liquor)) <p>The following risk factor may occur any time in the patient's history and must not start during the measurement period:</p> <ul style="list-style-type: none"> • Osteopenia <p>The following risk factors may occur at any time in the patient's history or during the measurement period:</p> <ul style="list-style-type: none"> • Rheumatoid arthritis • Hyperthyroidism • Malabsorption syndromes: celiac disease, inflammatory bowel disease, ulcerative colitis, Crohn's disease, cystic fibrosis, malabsorption • Chronic liver disease • Chronic malnutrition <p>The following risk factors may occur any time in the patient's history and do not need to be active at the start of the measurement period:</p> <ul style="list-style-type: none"> • Documentation of history of hip fracture in parent • Osteoporotic fracture • Glucocorticoids (>= 5 mg/per day) [cumulative medication duration >= 90 days] <p>Independent risk factors (The following risk factors are all independent risk factors; they are grouped by when they occur in relation to the measurement period):</p> <p>The following risk factors may occur at any time in the patient's history and must not start during the measurement period:</p> <ul style="list-style-type: none"> • Osteoporosis <p>The following risk factors may occur at any time in the patient's history prior to the start of the measurement period, but do not need to be active during the measurement period:</p> <ul style="list-style-type: none"> • Gastric bypass • FRAX[R] 10-year probability of all major osteoporosis related fracture >= 9.3 percent • Aromatase inhibitors <p>The following risk factors may occur at any time in the patient's history or during the measurement period:</p> <ul style="list-style-type: none"> • Type I diabetes • End stage renal disease • Osteogenesis imperfecta • Ankylosing spondylitis • Psoriatic arthritis • Ehlers-Danlos syndrome • Cushings syndrome • Hyperparathyroidism • Marfan's syndrome • Lupus
Measure Type:	Process
Measure Domain:	Efficiency and Cost Reduction
High Priority	Yes (Appropriate Use)

Category	Description
measure:	
Collection Type:	eCQM Specifications
Rationale:	<p>We are proposing to adopt this measure because it will serve as a counterbalance to the existing measure of appropriate use (that is, Screening for Osteoporosis for Women Aged 65-85 Years of Age (Quality ID #039)). This measure addresses the inappropriate use of DXA scans for women age 50 – 64 years without risk factors for osteoporosis. The MAP recognized the need for early detection of osteoporosis but reiterated the importance of appropriate use of this screening technique and noted this measure could be complementary to the existing osteoporosis screening measure (Quality ID #039). The MAP recognized the potential need for a balancing measure to prevent the potential underuse of DXA scans. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at the following link: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>

A.6. Average Change in Leg Pain Following Lumbar Spine Fusion Surgery

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	TBD
Description:	For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative leg pain to one year (nine to fifteen months) post-operative leg pain using the Visual Analog Scale (VAS) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	<p>The average change (preoperative to one year post-operative) in leg pain for all patients in the denominator.</p> <p>There is not a traditional numerator for this measure; the measure is calculating the average change in leg pain score from pre-operative to post-operative leg pain score. The measure is NOT aiming for a numerator target value for a post-operative pain score.</p> <p>The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose pain increases post-operatively. Example below:</p> <p>Patient I: Pre-op VAS I: Post-op VAS I:(Pre-op minus Post-op) Patient A: I: 8.5 I: 3.5 I: 5.0 Patient B: I: 9.0 I: 2.5 I: 6.5 Patient C: I: 7.0 I: 0.5 I: 6.5 Patient D: I: 6.5 I: 8.0 I: -1.5 Patient E I: 8.5 I: 2.0 I: 6.5 Patient F I: 7.5 I: 1.5 I: 6.0 Patient G I: 9.0 I: 4.5 I: 4.5 Patient H I: 5.5 I: 7.5 I: -2.0 Patient I I: 9.0 I: 5.0 I: 4.0 Patient J I: 7.0 I: 2.5 I: 4.5 Average change in VAS points 4.0 Average change in leg pain one year post-op 4.0 points on a 10 point scale.</p>
Denominator:	<p>Eligible Population: Patients with lumbar spine fusion procedures (Arthrodesis Value Set) occurring during a 12 month period for patients age 18 and older at the start of that period.</p> <p>Denominator: Patients within the eligible population whose leg pain was measured by the Visual Analog Scale (VAS) within three months preoperatively AND at one year (+/- 3 months) postoperatively.</p> <p>*The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed</p>
Exclusions:	<p>The following exclusions must be applied to the eligible population: Patient had cancer (Spine Cancer Value Set), fracture (Spine Fracture Value Set) or infection (Spine Infection Value Set) related to the spine. Patient had idiopathic or congenital scoliosis (Congenital Scoliosis Value Set)</p>
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High priority measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	<p>We are proposing to adopt this measure because it evaluates the management of pain from pre- to post-operative, which represents an important patient reported outcome. The results can be used by clinicians in evaluating whether the patient's pain has reduced post-operatively. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at the following link: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>

A.7. Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication

Category	Description
NQF #:	N/A
Quality #:	TBD
Description:	The percentage of patients 18-75 years of age who had a diagnosis of ischemic vascular disease (IVD) and were on daily aspirin or anti-platelet medication, unless allowed contraindications or exceptions are present.
Measure Steward:	Minnesota Community Measurement
Numerator:	Denominator patients with documentation that the patient was on daily aspirin or anti-platelet medication during the measurement period, unless allowed contraindications or exceptions are present.
Denominator:	18 years or older at the start of the measurement period AND less than 76 years at the end of the measurement period AND Patient had a diagnosis of ischemic vascular disease (Ischemic Vascular Disease Value Set) with any contact during the current or prior measurement period OR had ischemic vascular disease (Ischemic Vascular Disease Value Set) present on an active problem list at any time during the measurement period. AND At least one established patient office visit (Established Pt Diabetes & Vasc Value Set) for any reason during the measurement period
Exclusions:	The following exclusions are allowed to be applied to the eligible population: <ul style="list-style-type: none"> • Patient was a permanent nursing home resident at any time during the measurement period • Patient was in hospice or receiving palliative care at any time during the measurement period • Patient died prior to the end of the measurement period • Patient had only urgent care visits during the measurement period
Measure Type:	Process
Measure Domain:	Effective Clinical Care
High priority measure:	No
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Rationale:	<p>We are proposing to adopt this measure because the proposed measure exclusions are more appropriate than those in the currently adopted Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic (Quality ID #204) measure. The proposed measure accounts for history of gastrointestinal bleeding, intracranial bleeding, bleeding disorder, allergy to aspirin or anti-platelets, or use of non-steroidal anti-inflammatory agents. The MAP acknowledged both that clinicians may still report Aspirin or Anti-platelet Medication measures separately from the composite to drive quality improvement. The MAP conditionally supported this measure with the condition that there are no competing measures in the program. We refer readers to Table C where we are proposing to remove Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic (Quality ID #204).</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at the following link: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>

A.8. Zoster (Shingles) Vaccination

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	TBD
Description:	The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.
Measure Steward:	PPRNet
Numerator:	Patients with a shingles vaccine ever recorded.
Denominator:	Patients 50 years of age and older.
Exclusions:	None
Measure Type:	Process
Measure Domain:	Community/Population Health
High priority measure:	No
Collection Type:	MIPS CQMs Specifications
Rationale:	<p>We are proposing to adopt this measure because there are no measures currently in MIPS that address shingles vaccination for patients 60 years and older as recommended by the CDC. The MAP concluded that this measure would address the important topic of adult immunization. It discussed the new guidelines under development for the Zoster vaccination that could impact the amount of doses, the age of administration, and the specific vaccine that is used, but also noted that guidelines are constantly evolving and measures should be routinely updated based on changing guidelines. The MAP conditionally supported this measure pending NQF endorsement, and specifically requested evaluating the measure to ensure it has appropriate exclusions and reflects the most current CDC guidelines given the concerns about the cost of the vaccine and potential concerns about administering to immunocompromised patients. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at the following link: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>

A.9. HIV Screening

Category	Description
NQF #:	3067
Quality #:	TBD
Description:	Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).
Measure Steward:	Centers for Disease Control and Prevention
Numerator:	Patients with documentation of the occurrence of an HIV test between their 15th and 66th birthdays and before the end of the measurement period.
Denominator:	Patients 15 to 65 years of age who had an outpatient visit during the measurement period.
Exclusions:	Patients diagnosed with HIV prior to the start of the measurement period.
Measure Type:	Process
Measure Domain:	Community/Population Health
High priority measure:	No
Collection Type:	eCQM Specifications
Rationale:	<p>We are proposing to adopt this measure because HIV screening is a national and global priority. While there are three currently adopted HIV measures in MIPS, they do not include screening the general population. The MAP acknowledged the importance of HIV screening from a population health perspective, but also questioned whether encouraging HIV screening through the MIPS program is the most effective strategy for improving this population health goal. It also expressed concern about how this measure under consideration identified individuals who may have a HIV screening in the community. Additionally, several MAP members expressed concern regarding the specifications requiring one time lifetime screening. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at the following link: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>

A.10. Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Category	Description
NQF #:	0101
Quality #:	TBD
Description:	<p>This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>
Measure Steward:	National Committee for Quality Assurance
Numerator:	<p>This measure has three rates. The numerators for the three rates are as follows:</p> <p>A) Screening for Future Fall Risk: Patients who were screened for future fall* risk** at last once within 12 months B) Falls Risk Assessment: Patients who had a risk assessment*** for falls completed within 12 months C) Plan of Care for Falls: Patients with a plan of care**** for falls documented within 12 months.</p> <p>*A fall is defined as a sudden, unintentional change in position causing an individual to land at a lower level, on an object, the floor, or the ground, other than as a consequence of a sudden onset of paralysis, epileptic seizure, or overwhelming external force.</p> <p>**Risk of future falls is defined as having had 2 or more falls in the past year or any fall with injury in the past year.</p> <p>***Risk assessment is comprised of balance/gait assessment AND one or more of the following assessments: postural blood pressure, vision, home fall hazards, and documentation on whether medications are a contributing factor or not to falls within the past 12 months.</p> <p>****Plan of care must include consideration of vitamin D supplementation AND balance, strength and gait training.</p>
Denominator:	<p>A) Screening for Future Fall Risk: All patients aged 65 years and older seen by an eligible provider in the past year.</p> <p>B & C) Falls Risk Assessment & Plan of Care for Falls: All patients aged 65 years and older seen by an eligible provider in the past year with a history of falls (history of falls is defined as 2 or more falls in the past year or any fall with injury in the past year).</p>
Exclusions:	Patients who have documentation of medical reason(s) for not screening for future fall risk, undergoing a risk-assessment or having a plan of care (e.g., patient is not ambulatory) are excluded from this measure.
Measure Type:	Process
Measure Domain:	Patient Safety
High Priority Measure:	Yes
Collection Type:	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Rationale:	<p>We are proposing to adopt this measure because it is a combined version of three of the currently adopted measures 154: Falls: Risk Assessment, 155: Falls: Plan of Care and 318: Falls: Screening for Future Fall Risk. The new combined Falls measure (based on specifications in NQF 0101) is more robust and will include strata components for Future Falls Risk, Falls Risk Assessment, and Falls Risk Plan of Care which creates a more comprehensive screening measure. As noted in Table C, we are proposing to remove 154: Falls: Risk Assessment, 155: Falls: Plan of Care and 318: Falls: Screening for Future Fall Risk because they will be subsumed by this new measure. While we note that has not been put forth through the MAP for consideration in MIPS, the three individual measures have been NQF endorsed as one measure.</p>

TABLE Group B: Proposed New and Modified MIPS Specialty Measure Sets for the 2021 MIPS Payment Year and Future Years

Note: In this proposed rule, CMS proposes to modify the specialty measure sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies. In the first column, existing measures with substantive changes are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§) and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a “high priority type” in parentheses after each high priority indicator (!) to fully represent the regulatory definition of high priority measures.

As discussed in section III.H.3.h.(2)(b)(i) of this proposed rule, we are proposing to amend the definition of high priority at §414.1305 to include opioid-related measures. We define high priority measure to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures include outcome, intermediate outcome, and patient reported outcome. A high priority indicator (an exclamation point (!)) in the Indicator column has been added for all opioid-related measures.

The following specialty measure sets have been excluded from this proposed rule, because we are not proposing any changes to these sets: Allergy/Immunology, Electro-Physiology Cardiac Specialist, Plastic Surgery, Interventional Radiology, and Hospitalists. Therefore, we refer readers to these finalized specialty sets in the CY 2018 Quality Payment Program final rule (82 FR 53976 through 54146).

B.1. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Anesthesiology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Anesthesiology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 426 and 427.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0236	044	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery: Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections: Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
! (Outcome)	N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Anesthesiology Smoking Abstinence: The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	2681	424	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Perioperative Temperature Management: Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A	430	N/A	MIPS CQMs Specifications	Process	Patient Safety	Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy: Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively or intraoperatively.	American Society of Anesthesiologists

B.1. Anesthesiology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	463	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Prevention of Post-Operative Vomiting (POV) - Combination Therapy (Pediatrics): Percentage of patients aged 3 through 17 years of age, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists

B.1. Anesthesiology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	426	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU): Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU or other non-ICU location in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.	American Society of Anesthesiologists	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future."
N/A	427	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU): Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member.	American Society of Anesthesiologists	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.2. Cardiology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Cardiology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Cardiology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 204 and 373.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	TBD	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication: The percentage of patients 18-75 years of age who had a diagnosis of ischemic vascular disease (IVD) and were on daily aspirin or anti-platelet medication, unless allowed contraindications or exceptions are present.	Minnesota Community Measurement
§	0081	005	135v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Chronic Stable Coronary Artery Disease: Antiplatelet Therapy: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	145v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI OR a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.2. Cardiology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0083	008	144v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Chronic Stable Coronary Artery Disease: ACE Inhibitor or ARB Therapy--Diabetes or Left Ventricular Systolic Dysfunction (LVEF <40%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services

B.2. Cardiology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	165v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance

B.2. Cardiology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0022	238	156v6	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Use of High-Risk Medications in the Elderly: Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Cardiac Rehabilitation Patient Referral from an Outpatient Setting: Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP).	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients: Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low risk surgery patients 18 years or older for preoperative evaluation during the 12-month reporting period.	American College of Cardiology

B.2. Cardiology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Efficiency)	N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI): Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology
! (Efficiency)	N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients: Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Chronic Anticoagulation Therapy: Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism.	American College of Cardiology
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2): Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons

B.2. Cardiology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive: Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Population/Community	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI)
	N/A	438	347v1	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: <ul style="list-style-type: none"> • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥ 21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL. 	Centers for Medicare & Medicaid Services

B.2. Cardiology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	<p>Ischemic Vascular Disease All or None Outcome Measure (Optimal Control): The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator, optimal results include:</p> <ul style="list-style-type: none"> • Most recent blood pressure (BP) measurement is less than 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated • Statin Use Unless Contraindicated 	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§	0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Persistent Beta Blocker Treatment After a Heart Attack: The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for six months after discharge.</p>	National Committee for Quality Assurance

B.2. Cardiology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0068	204	164v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet: Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	373	65v7	eCQM Specifications	Intermediate Outcome	Effective Clinical Care	Hypertension: Improvement in Blood Pressure: Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.3. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Gastroenterology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Gastroenterology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measure from the specialty set: Quality ID: 185.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m ² .	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.3. Gastroenterology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	271	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment: Percentage of patients with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year. Individuals who received an assessment for bone loss during the prior or current year are considered adequately screened.	American Gastroenterological Association
§	N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association

B.3. Gastroenterology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients: Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
§ ! (Outcome)	N/A	343	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Screening Colonoscopy Adenoma Detection Rate Measure: The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy.	American Gastroenterological Association
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.3. Gastroenterology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	425	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Photodocumentation of Cecal Intubation: The rate of screening and surveillance colonoscopies for which photo documentation of landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointestinal Endoscopy
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Efficiency)	N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Age Appropriate Screening Colonoscopy: The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.	American Gastroenterological Association

B.3. Gastroenterology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Experience)	N/A	390	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	<p>Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient.</p> <p>To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.</p>	American Gastroenterological Association
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period.</p>	American Gastroenterological Association
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	<p>Tobacco Use and Help with Quitting Among Adolescents:</p> <p>The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.</p>	National Committee for Quality Assurance

B.3. Gastroenterology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0659	185	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use: Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.4. Dermatology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Dermatology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Dermatology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measure from the specialty set: Quality ID: 224.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0650	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	Melanoma: Continuity of Care – Recall System: Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: <ul style="list-style-type: none"> • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment. 	American Academy of Dermatology
! (Care Coordination)	N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Melanoma: Coordination of Care: Percentage of patients visits, regardless of age, with a new occurrence of melanoma, who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology

B.4. Dermatology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS F-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Biopsy Follow-Up: Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician.	American Academy of Dermatology
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier: Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology

B.4 Dermatology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Outcome)	N/A	410	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Person and Caregiver Centered Experience and Outcomes	Psoriasis: Clinical Response to Oral Systemic or Biologic Medications: Percentage of psoriasis vulgaris patients receiving systemic therapy who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment	American Academy of Dermatology
! (Care Coordination)	N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma: Biopsy Reporting Time – Pathologist to Clinician: Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician: Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.4 Dermatology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0562	224	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Melanoma: Overutilization of Imaging Studies in Melanoma: Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.	American Academy of Dermatology	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.5. Family Medicine

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Family Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Family Medicine specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 048, 154, 155, 163, 204, 318, 334, 373, and 447.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	TBD	TBD	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	<p>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>	National Committee for Quality Assurance
! (Opioid)	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Continuity of Pharmacotherapy for Opioid Use Disorder: Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment</p>	University of Southern California
	N/A	TBD	TBD	eCQM Specifications	Process	Community/Population Health	<p>HIV Screening: Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).</p>	Centers for Disease Control and Prevention
! (Appropriate Use)	N/A	TBD	TBD	eCQM Specifications	Process	Efficiency and Cost Reduction	<p>Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture: Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.</p>	Centers for Medicare & Medicaid Services

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	TBD	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication: The percentage of patients 18-75 years of age who had a diagnosis of ischemic vascular disease (IVD) and were on daily aspirin or anti-platelet medication, unless allowed contraindications or exceptions are present.	Minnesota Community Measurement
	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Zoster (Shingles) Vaccination: The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
! (Opioid)	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Continuity of Pharmacotherapy for Opioid Use Disorder: Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment	University of Southern California
§ ! (Outcome)	0059	001	122v6	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications, eCQM Specifications	Intermediate Outcome	Effective Clinical Care	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%): Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
§	0081	005	135v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Chronic Stable Coronary Artery Disease: Antiplatelet Therapy: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	145v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI OR a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0083	008	144v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0105	009	128v6	eCQM Specifications	Process	Effective Clinical Care	Anti-Depressant Medication Management: Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment. Two rates are reported a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks) b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	0045	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	/Communication and Care Coordination	Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older: Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Screening for Osteoporosis for Women Aged 65-85 Years of Age: Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
! (Appropriate Use)	0069	065	154v6	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Appropriate Treatment for Children with Upper Respiratory Infection (URI): Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode.	National Committee for Quality Assurance

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Appropriate Use)	N/A	066	146v6	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Appropriate Testing for Children with Pharyngitis: Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Acute Otitis Externa (AOE): Topical Therapy: Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use: Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology - Head and Neck Surgery
	0104	107	161v6	eCQM Specifications	Process	Effective Clinical Care	Adult Major Depressive Disorder (MDD): Suicide Risk Assessment: Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Patient Experience)	N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	Osteoarthritis (OA): Function and Pain Assessment: Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0041	110	147v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	0043	111	127v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	Pneumococcal Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§	2372	112	125v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Breast Cancer Screening: Percentage of women 50 -74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0034	113	130v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Colorectal Cancer Screening: Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis: The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
* §	0055	117	131v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Diabetes: Eye Exam: Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0062	119	134v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Diabetes: Medical Attention for Nephropathy: The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	2v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Elder Maltreatment Screen and Follow-Up Plan: Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	165v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0022	238	156v6	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Use of High-Risk Medications in the Elderly: Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Cardiac Rehabilitation Patient Referral from an Outpatient Setting: Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation
! (Opioid)	0004	305	137v6	eCQM Specifications	Process	Effective Clinical Care	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. <ul style="list-style-type: none"> Percentage of patients who initiated treatment within 14 days of the diagnosis. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit. 	National Committee for Quality Assurance
§	0032	309	124v6	eCQM Specifications	Process	Effective Clinical Care	Cervical Cancer Screening: Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria: <ul style="list-style-type: none"> Women age 21–64 who had cervical cytology performed every 3 years Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years. 	National Committee for Quality Assurance

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	0005 & 0006	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	CAHPS for MIPS Clinician/Group Survey: The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: <ul style="list-style-type: none"> • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF) 	Agency for Healthcare Research & Quality (AHRQ) Centers for Medicare & Medicaid Services
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy: Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse): Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier: Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	HIV Viral Load Suppression: The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
! (Outcome)	N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	Pain Brought Under Control Within 48 Hours: Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* § ! (Outcome)	0710	370	159v6	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	Depression Remission at Twelve Months: The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
*	0712	371	160v6	eCQM Specifications	Process	Effective Clinical Care	Depression Utilization of the PHQ-9 Tool: The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period.	MN Community Measurement
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	377	90v7	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Functional Status Assessments for Congestive Heart Failure: Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	Adherence to Antipsychotic Medications for Individuals with Schizophrenia: Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Health Services Advisory Group
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users: Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12 month reporting period	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	1407	394	N/A	MIPS CQMs Specifications	Process	Community / Population Health	Immunizations for Adolescents: The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Optimal Asthma Control: Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools.	Minnesota Community Measurement
§	3059	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk: Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period.	American Gastroenterological Association
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Opioid Therapy Follow-up Evaluation: All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Documentation of Signed Opioid Treatment Agreement: All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Evaluation or Interview for Risk of Opioid Misuse: All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Osteoporosis Management in Women Who Had a Fracture: The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	438	347v1	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥ 21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Ischemic Vascular Disease All or None Outcome Measure (Optimal Control): The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: <ul style="list-style-type: none"> • Most recent blood pressure (BP) measurement is less than 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated • Statin Use Unless Contraindicated 	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Persistent Beta Blocker Treatment After a Heart Attack: The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	Non-Recommended Cervical Cancer Screening in Adolescent Females: The percentage of adolescent females 16–20 years of age screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	1799	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Medication Management for People with Asthma (MMA): The percentage of patients 5–64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
! (Patient Safety)	0657	464	N/A	MIPS CQMs Specifications	Process	Patient Safety, Efficiency, and Cost Reduction	Otitis Media with Effusion (OME); Systemic Antimicrobials- Avoidance of Inappropriate Use: Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNHF)

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0056	163	123v6	eCQM Specifications	Process	Effective Clinical Care	Comprehensive Diabetes Care: Foot Exam: The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0068	204	164v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet: Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
0101	318	139v6	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	Falls: Screening for Future Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
N/A	334	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.5. Family Medicine (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	373	65v7	eCQM Specifications	Intermediate Outcome	Effective Clinical Care	Hypertension: Improvement in Blood Pressure: Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	447	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Chlamydia Screening and Follow Up: The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.6. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Internal Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Internal Medicine specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 048, 154, 155, 163, 204, 276, 278, 318, 334, 373, and 447.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	TBD	TBD	Part B Claims Measure Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	<p>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>	National Committee for Quality Assurance
! (Opioid)	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Continuity of Pharmacotherapy for Opioid Use Disorder: Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment</p>	University of Southern California
	N/A	TBD	TBD	eCQM Specifications	Process	Community/Population Health	<p>HIV Screening: Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).</p>	Centers for Disease Control and Prevention

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Appropriate Use)	N/A	TBD	TBD	eCQM Specifications	Process	Efficiency and Cost Reduction	Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture: Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
	N/A	TBD	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication: The percentage of patients 18-75 years of age who had a diagnosis of ischemic vascular disease (IVD) and were on daily aspirin or anti-platelet medication, unless allowed contraindications or exceptions are present.	Minnesota Community Measurement
	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Zoster (Shingles) Vaccination: The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
§ ! (Outcome)	0059	001	122v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%): Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0081	005	135v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0083	008	144v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium For Performance Improvement
	0105	009	128v6	eCQM Specifications	Process	Effective Clinical Care	Anti-Depressant Medication Management: Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment. Two rates are reported a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks) b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	0045	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older: Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Screening for Osteoporosis for Women Aged 65-85 Years of Age: Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
! (Appropriate Use)	0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Acute Otitis Externa (AOE): Topical Therapy: Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use: Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
	0041	110	147v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	0043	111	127v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Pneumococcal Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis: Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription	National Committee for Quality Assurance
* §	0055	117	131v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Diabetes: Eye Exam: Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0062	119	134v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Diabetes: Medical Attention for Nephropathy: The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0418	134	2v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Elder Maltreatment Screen and Follow-Up Plan: Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ ! (Outcome)	0018	236	165v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022	238	156v6	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Use of High-Risk Medications in the Elderly: Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Cardiac Rehabilitation Patient Referral from an Outpatient Setting: Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Sleep Apnea: Severity Assessment at Initial Diagnosis: Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis	American Academy of Sleep Medicine

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured	American Academy of Sleep Medicine
! (Opioid)	0004	305	137v6	eCQM Specifications	Process	Effective Clinical Care	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. <ul style="list-style-type: none"> Percentage of patients who initiated treatment within 14 days of the diagnosis. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit. 	National Committee for Quality Assurance
§	0032	309	124v6	eCQM Specifications	Process	Effective Clinical Care	Cervical Cancer Screening: Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria: <ul style="list-style-type: none"> Women age 21–64 who had cervical cytology performed every 3 years Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years. 	National Committee for Quality Assurance
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ ! (Patient Experience)	0005	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	CAHPS for MIPS Clinician/Group Survey: The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ) Centers for Medicare & Medicaid Services
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy: Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA- approved anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse): Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier: Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	HIV Viral Load Suppression: The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	Pain Brought Under Control Within 48 Hours: Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* § ! (Outcome)	0710	370	159v6	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	Depression Remission at Twelve Months: The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	MN Community Measurement
*	0712	371	160v6	eCQM Specifications	Process	Effective Clinical Care	Depression Utilization of the PHQ-9 Tool: The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period.	MN Community Measurement
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	377	90v7	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Functional Status Assessments for Congestive Heart Failure: Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	Adherence to Antipsychotic Medications for Individuals with Schizophrenia: Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Health Services Advisory Group
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users: Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12 month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Optimal Asthma Control: Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools.	Minnesota Community Measurement
§	3059	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk: Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period.	American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Opioid Therapy Follow-up Evaluation: All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Documentation of Signed Opioid Treatment Agreement: All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Evaluation or Interview for Risk of Opioid Misuse: All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Osteoporosis Management in Women Who Had a Fracture: The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	438	347v1	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of the following patients: all considered at high risk of cardiovascular events who were prescribed or were on statin therapy during the measurement period: <ul style="list-style-type: none"> • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥ 21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL. 	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Ischemic Vascular Disease All or None Outcome Measure (Optimal Control): The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: <ul style="list-style-type: none"> • Most recent blood pressure (BP) measurement is less than 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated • Statin Use Unless Contraindicated 	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§	0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Persistent Beta Blocker Treatment After a Heart Attack: The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ ! (Patient Safety)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	Non-Recommended Cervical Cancer Screening in Adolescent Females: The percentage of adolescent females 16–20 years of age screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	1799	444	NA	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Medication Management for People with Asthma (MMA): The percentage of patients 5–64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0056	163	123v6	eCQM Specifications	Process	Effective Clinical Care	Comprehensive Diabetes Care: Foot Exam: The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0068	204	164v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet: Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
N/A	276	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Sleep Apnea: Assessment of Sleep Symptoms: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness	American Academy of Sleep Medicine	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
N/A	278	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Sleep Apnea: Positive Airway Pressure Therapy Prescribed: Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy	American Academy of Sleep Medicine	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.6. Internal Medicine (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0101	318	139v6	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	Falls: Screening for Future Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	334	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	373	65v7	eCQM Specifications	Intermediate Outcome	Effective Clinical Care	Hypertension: Improvement in Blood Pressure: Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	447	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Chlamydia Screening and Follow Up: The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.7. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the Emergency Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the Emergency Medicine specialty set. This measure set does not have any measures that are proposed for removal from prior years.

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Efficiency)	N/A	066	146v6	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Appropriate Testing for Children with Pharyngitis: Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0653	091	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Acute Otitis Externa (AOE): Topical Therapy: Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	0654	093	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use: Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
	0104	107	161v6	eCQM Specifications	Process	Effective Clinical Care	Adult Major Depressive Disorder (MDD): Suicide Risk Assessment: Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis: Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription.	National Committee for Quality Assurance

B.7. Emergency Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Stroke and Stroke Rehabilitation: Thrombolytic Therapy: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV t-PA was initiated within three hours of time last known well.	American Heart Association
	N/A	254	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain: Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
	N/A	255	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure: Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED).	American College of Emergency Physicians
	N/A	317	22v6	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse): Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery

B.7. Emergency Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
* ! (Efficiency)	N/A	415	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older: Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
* ! (Efficiency)	N/A	416	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years: Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.8. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Obstetrics/Gynecology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Obstetrics/Gynecology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 048, 369, and 447.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Appropriate Use)		TBD	TBD	eCQM Specifications	Process	Efficiency and Cost Reduction	Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture: Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
		TBD	TBD	eCQM Specifications	Process	Community/Population Health	HIV Screening: Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance

B.8. Obstetrics/Gynecology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0041	110	147v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	2372	112	125v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Breast Cancer Screening: Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services

B.8. Obstetrics/Gynecology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	165v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Biopsy Follow Up: Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician.	American Academy of Dermatology

B.8. Obstetrics/Gynecology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0032	309	124v6	eCQM Specifications	Process	Effective Clinical Care	Cervical Cancer Screening: Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21–64 who had cervical cytology performed every 3 years • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
	0033	310	153v6	eCQM Specifications	Process	Community/Population Health	Chlamydia Screening for Women: Percentage of women 16–24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.8. Obstetrics/Gynecology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Osteoporosis Management in Women Who Had a Fracture: The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury: Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society
	N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence: Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per ACOG/AUGS/AUA guidelines.	American Urogynecologic Society
! (Patient Safety)	N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy: Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.8. Obstetrics/Gynecology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair: Percentage of patients undergoing any surgery to repair pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 1 month after surgery.	American Urogynecologic Society
! (Outcome)	N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Proportion of Patients Sustaining a Bowel Injury at the Time of any Pelvic Organ Prolapse Repair: Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 1 month after surgery.	American Urogynecologic Society
! (Outcome)	N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Proportion of Patients Sustaining A Ureter Injury at the Time of any Pelvic Organ Prolapse Repair: Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 1 month after surgery.	American Urogynecologic Society
§ ! (Patient Safety)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	Non-Recommended Cervical Cancer Screening in Adolescent Females: The percentage of adolescent females 16–20 years of age screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Care Coordination)	0567	448	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Appropriate Work Up Prior to Endometrial Ablation: Percentage of women, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
*	0043	111	127v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Pneumococcal Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance

B.8. Obstetrics/Gynecology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
N/A	369	158v6	eCQM Specifications	Process	Effective Clinical Care	Pregnant women that had HBsAg testing: This measure identifies pregnant women who had an HBsAg (hepatitis B) test during their pregnancy.	OptumInsight	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
N/A	447	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Chlamydia Screening and Follow Up: The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.9. Ophthalmology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Ophthalmology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Ophthalmology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 012, 018, and 140.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0087	014	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Age-Related Macular Degeneration (AMD): Dilated Macular Examination: Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months.	American Academy of Ophthalmology
! (Care Coordination)	0089	019	142v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0055	117	131v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Clinical Care	Diabetes: Eye Exam: Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance

B.9. Ophthalmology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Outcome)	0563	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Communication and Care Coordination	Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care: Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within 12 months.	American Academy of Ophthalmology
! (Outcome)	0565	191	133v6	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.9. Ophthalmology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	0564	192	132v6	eCQM Specifications, MIPS CQMs Specifications	Outcome	Patient Safety	Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	1536	303	N/A	MIPS CQMs Specifications	Outcome	Person Caregiver-Centered Experience and Outcomes	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology

B.9. Ophthalmology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	384	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery: Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
! (Outcome)	N/A	385	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery: Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A	388	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy): Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy.	American Academy of Ophthalmology
! (Outcome)	N/A	389	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Cataract Surgery: Difference Between Planned and Final Refraction: Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 0.5 diopters of their planned (target) refraction.	American Academy of Ophthalmology

B.9. Ophthalmology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0086	012	143v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation: Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
0088	018	167v6	eCQM Specifications	Process	Effective Clinical Care	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
0566	140	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement: Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) or their caregiver(s) who were counseled within 12 months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for preventing progression of AMD.	American Academy of Ophthalmology	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.10. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Family Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Family Medicine specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 154, 155, and 375.

MEASURES PROPOSED FOR INCLUSION								
Indicator(High Priority Type)	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	TBD	TBD	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	<p>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>	National Committee for Quality Assurance
! (Outcome)	2643	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	<p>Average Change in Functional Status Following Lumbar Spine Fusion Surgery: For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative functional status to one year (nine to fifteen months) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.</p>	Minnesota Community Measurement
! (Outcome)	2653	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	<p>Average Change in Functional Status Following Total Knee Replacement Surgery: For patients age 18 and older undergoing total knee replacement surgery, the average change from pre-operative functional status to one year (nine to fifteen months) post-operative functional status using the Oxford Knee Score (OKS) patient reported outcome tool.</p>	Minnesota Community Measurement

B.10. Orthopedic Surgery (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator(High Priority Type)	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery: For patients age 18 and older undergoing lumbar discectomy laminotomy surgery, the average change from pre-operative functional status to three months (6 to 20 weeks) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.	Minnesota Community Measurement
! (Patient Experience)	N/A	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	Average Change in Leg Pain Following Lumbar Spine Fusion Surgery: For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative leg pain to one year (nine to fifteen months) post-operative leg pain using the Visual Analog Scale (VAS) patient reported outcome tool.	Minnesota Community Measurement
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons

B.10. Orthopedic Surgery (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0239	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0045	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older: Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
§! (Care Coordination)*	0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Medication Reconciliation Post-Discharge: The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age • Submission Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older	National Committee for Quality Assurance

B.10. Orthopedic Surgery (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Osteoarthritis (OA): Function and Pain Assessment: Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.10. Orthopedic Surgery (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
	0418	134	2v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
	N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Functional Status Assessment: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology
	N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Glucocorticoid Management Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology

B.10. Orthopedic Surgery (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	350	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy: Percentage of patients regardless of age undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g. nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A	351	N/A	MIPS CQMs Specifications	Process	Patient Safety	Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation: Percentage of patients regardless of age undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g. history of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons

B.10. Orthopedic Surgery (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	N/A	352	N/A	MIPS CQMs Specifications	Process	Patient Safety	Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet: Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A	353	N/A	MIPS CQMs Specifications	Process	Patient Safety	Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report: Percentage of patients regardless of age undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.	American Association of Hip and Knee Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication: Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	376	56v6	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Functional Status Assessment for Total Hip Replacement: Percentage of patients 18 years of age and older with who received an elective primary total hip arthroplasty (THA) who completed baseline and follow-up patient-reported and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.10. Orthopedic Surgery (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Opioid Therapy Follow-up Evaluation: All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Documentation of Signed Opioid Treatment Agreement: All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Evaluation or Interview for Risk of Opioid Misuse: All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology
	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Osteoporosis Management in Women Who Had a Fracture: The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* ! (Outcome)	N/A	459	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	Average Change in Back Pain Following Lumbar Discectomy / Laminotomy: The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had lumbar discectomy /laminotomy procedure	MN Community Measurement
* ! (Outcome)	N/A	460	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	Average Change in Back Pain Following Lumbar Fusion: The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had lumbar spine fusion surgery	MN Community Measurement
* ! (Outcome)	N/A	461	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	Average Change in Leg Pain Following Lumbar Discectomy / Laminotomy: The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had lumbar discectomy / laminotomy procedure	MN Community Measurement

B.10. Orthopedic Surgery (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	375	66v6	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Functional Status Assessment for Total Knee Replacement: Changes to the measure description: Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) who completed baseline and follow-up patient-reported and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.11. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Otolaryngology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Otolaryngology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 154, 155, 276, 278, 318, and 334.

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	TBD	TBD	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	<p>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>	National Committee for Quality Assurance
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	<p>Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis</p>	American Society of Plastic Surgeons
! (Patient Safety)	0239	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	<p>Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time</p>	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	<p>Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.</p>	National Committee for Quality Assurance

B.11. Otolaryngology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Appropriate Use)	0069	065	154v6	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Appropriate Treatment for Children with Upper Respiratory Infection (URI): Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode	National Committee for Quality Assurance
! (Appropriate Use)	0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Acute Otitis Externa (AOE): Topical Therapy: Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use: Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy	American Academy of Otolaryngology-Head and Neck Surgery
	0041	110	147v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	0043	111	127v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	Pneumococcal Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance

B.11. Otolaryngology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Biopsy Follow Up: Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician	American Academy of Dermatology
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Sleep Apnea: Severity Assessment at Initial Diagnosis: Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis	American Academy of Sleep Medicine

B.11. Otolaryngology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured	American Academy of Sleep Medicine
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse): Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
! (Efficiency)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery

B.11. Otolaryngology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Surgical Site Infection (SSI): Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication: Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Optimal Asthma Control: Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools	Minnesota Community Measurement
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Patient Safety)	0657	464	N/A	MIPS CQMs Specifications	Process	Patient Safety, Efficiency, and Cost Reduction	Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use: Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF)

B.11. Otolaryngology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	276	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Sleep Apnea: Assessment of Sleep Symptoms: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness	American Academy of Sleep Medicine	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.11. Otolaryngology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	278	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Sleep Apnea: Positive Airway Pressure Therapy Prescribed: Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy	American Academy of Sleep Medicine	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0101	318	139v6	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	Falls: Screening for Future Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	334	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.12. Pathology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Pathology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Pathology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 099, 100, and 251.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	1854	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Barrett's Esophagus: Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia	College of American Pathologists
§	1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Radical Prostatectomy Pathology Reporting: Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status	College of American Pathologists
! (Care Coordination)	N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Lung Cancer Reporting (Biopsy/ Cytology Specimens): Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary nonsmall cell lung cancer classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report	College of American Pathologists
! (Care Coordination)	N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Lung Cancer Reporting (Resection Specimens): Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer, histologic type	College of American Pathologists

B.12. Pathology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* ! (Care Coordination)	N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Melanoma Reporting: Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate	College of American Pathologists

B.12. Pathology

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0391	099	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade: Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade	College of American Pathologists	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
0392	100	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade: Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade	College of American Pathologists	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
1855	251	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Effective Clinical Care	Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients: This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the current ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer	College of American Pathologists	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.13. Pediatrics

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Pediatrics specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Pediatrics specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measure from the specialty set: Quality ID: 447.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Appropriate Use)	0069	065	154v6	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Appropriate Treatment for Children with Upper Respiratory Infection (URI): Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode.	National Committee for Quality Assurance
! (Appropriate Use)	N/A	066	146v6	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Appropriate Testing for Children with Pharyngitis: Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Acute Otitis External (AOE): Topical Therapy: Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Acute Otitis External (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use: Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy	American Academy of Otolaryngology-Head and Neck Surgery

B.13. Pediatrics (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0041	110	147v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0418	134	2v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	Preventive Care and Screening: Screening for Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	Centers for Medicare & Medicaid Services
§	0405	160	52v6	eCQM Specifications	Process	Effective Clinical Care	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis: Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis	National Committee for Quality Assurance
§	0409	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection	National Committee for Quality Assurance

B.13. Pediatrics (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0024	239	155v6	eCQM Specifications	Process	Community/Population Health	Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents: Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. <ul style="list-style-type: none"> Percentage of patients with height, weight, and body mass index (BMI) percentile documentation Percentage of patients with counseling for nutrition Percentage of patients with counseling for physical activity 	National Committee for Quality Assurance
	0038	240	117v6	eCQM Specifications	Process	Community/Population Health	Childhood Immunization Status: Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV); one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday	National Committee for Quality Assurance
! (Opioid)	0004	305	137v6	eCQM Specifications	Process	Effective Clinical Care	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. <ul style="list-style-type: none"> Percentage of patients who initiated treatment within 14 days of the diagnosis. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit. 	National Committee for Quality Assurance
	0033	310	153v6	eCQM Specifications	Process	Community/Population Health	Chlamydia Screening for Women: Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period	National Committee for Quality Assurance

B.13. Pediatrics (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0108	366	136v7	eCQM Specifications	Process	Effective Clinical Care	ADHD: Follow-Up Care for Children Prescribed ADHD Medication (ADD): Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended	National Committee for Quality Assurance
	N/A	379	74v7	eCQM Specifications	Process	Effective Clinical Care	Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists: Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period	Centers for Medicare & Medicaid Services
! (Patient Safety)	1365	382	177v6	eCQM Specifications	Process	Patient Safety	Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment: Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0576	391	N/A	MIPS CQMs Specifications	Process	Communication/Care Coordination	Follow-up After Hospitalization for Mental Illness (FUH): The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days of discharge • The percentage of discharges for which the patient received follow-up within 7 days of discharge	National Committee for Quality Assurance

B.13. Pediatrics (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	1407	394	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Immunizations for Adolescents: The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday	National Committee for Quality Assurance
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Optimal Asthma Control: Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools	Minnesota Community Measurement
	N/A	402	NA	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
§ ! (Efficiency)	1799	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Medication Management for People with Asthma (MMA): The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
! (Patient Safety)	0657	464	N/A	MIPS CQMs Specifications	Process	Patient Safety, Efficiency, and Cost Reduction	Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use: Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNHF)
	1448	467	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Developmental Screening in the First Three Years of Life: The percentage of children screened for risk of developmental, behavioral and social delays using a standardized screening tool in the first three years of life. This is a measure of screening in the first three years of life that includes three, age-specific indicators assessing whether children are screened by 12 months of age, by 24 months of age and by 36 months of age.	Oregon Health & Science University

B.13. Pediatrics (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	447	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Chlamydia Screening and Follow Up: The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.14. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Physical Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Physical Medicine specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 154, 155, and 318.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	TBD	TBD	Medicare Part B Claims Measure Specification s, CMS Web Interface Measure Specification s, MIPS CQMs Specification s	Process	Patient Safety	<p>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>	National Committee for Quality Assurance
! (Opioid)	N/A	TBD	N/A	MIPS CQMs Specification s	Process	Effective Clinical Care	<p>Continuity of Pharmacotherapy for Opioid Use Disorder: Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment</p>	University of Southern California
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specification s, MIPS CQMs Specification s	Process	Communication and Care Coordination	<p>Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.</p>	National Committee for Quality Assurance

B.14. Physical Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Experience)	N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Osteoarthritis (OA): Function and Pain Assessment: Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain	American Academy of Orthopedic Surgeons
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.14. Physical Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	Centers for Medicare & Medicaid Services
! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Functional Outcome Assessment: Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies	Centers for Medicare & Medicaid Services
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.14. Physical Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Opioid Therapy Follow-up Evaluation: All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Documentation of Signed Opioid Treatment Agreement: All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Evaluation or Interview for Risk of Opioid Misuse: All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.14. Physical Medicine (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
0101	318	139v6	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	Falls: Screening for Future Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.15. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Preventive Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Preventive Medicine specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 014, 154, and 155.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	TBD	TBD	eCQM Specifications	Process	Community/Population Health	HIV Screening: Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention
	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Zoster (Shingles) Vaccination: The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
§ ! (Outcome)	0059	001	122v6	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications, eCQM Specifications	Intermediate Outcome	Effective Clinical Care	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%): Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period	National Committee for Quality Assurance
! (Care Coordination)	0045	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older: Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication	National Committee for Quality Assurance

B.15. Preventive Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Screening for Osteoporosis for Women Aged 65-85 Years of Age: Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Osteoarthritis (OA): Function and Pain Assessment: Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain	American Academy of Orthopedic Surgeons
	0041	110	147v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	0043	111	127v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Pneumococcal Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance

B.15. Preventive Medicine (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	2372	112	125v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Breast Cancer Screening: Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer	National Committee for Quality Assurance
§	0034	113	130v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Colorectal Cancer Screening: Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis: Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription	National Committee for Quality Assurance

B.15. Preventive Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0062	119	134v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Diabetes: Medical Attention for Nephropathy: The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.15. Preventive Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0418	134	2v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	Centers for Medicare & Medicaid Services
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.15. Preventive Medicine (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	NA	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
	2152	431	NA	MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	438	347v1	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	/Effective Clinical Care	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥ 21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services

B.15. Preventive Medicine (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.16. Neurology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Neurology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Neurology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 154, 155, 318, and 386.

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	TBD	TBD	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	<p>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	<p>Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.</p>	National Committee for Quality Assurance

B.16. Neurology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	2v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	Centers for Medicare & Medicaid Services
! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Elder Maltreatment Screen and Follow-Up Plan: Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.16.Neurology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	1814	268	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy: All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year	American Academy of Neurology
	2872	281	149v6	eCQM Specifications	Process	Effective Clinical Care	Dementia: Cognitive Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Dementia: Functional Status Assessment: Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association and American Academy of Neurology
	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Dementia: Associated Behavioral and Psychiatric Symptoms Screening and Management: Percentage of patients with dementia for whom there was a documented symptoms screening for behavioral and psychiatric symptoms, including depression, AND for whom, if symptoms screening was positive, there was also documentation of recommendations for symptoms management in the last 12 months.	American Psychiatric Association and American Academy of Neurology

B.16. Neurology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	<p>Safety Concern Screening and Follow-Up for Patients with Dementia: Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety screening * in two domains of risk: dangerousness to self or others and environmental risks; and if screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.</p> <p>Note: The measure title description have been updated due to inconsistencies between the measure tables as provided in the proposed rule.</p>	American Psychiatric Association and American Academy of Neurology
! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	<p>Dementia: Caregiver Education and Support: Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12-month period</p>	American Psychiatric Association and American Academy of Neurology
	N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease: Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms in the past 12 months.</p>	American Academy of Neurology
	N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment: Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction in the past 12 months.</p>	American Academy of Neurology

B.16. Neurology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Opioid Therapy Follow-up Evaluation: All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Documentation of Signed Opioid Treatment Agreement: All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record	American Academy of Neurology

B.16. Neurology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Evaluation or Interview for Risk of Opioid Misuse: All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology
! (Efficiency) *	N/A	419	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Overuse Of Imaging For Patients With Primary Headache: Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Population/Community	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI)
! (Outcome)	N/A	435	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	Quality Of Life Assessment For Patients With Primary Headache Disorders: Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12 month measurement period AND whose health related quality of life score stayed the same or improved	American Academy of Neurology

B.16. Neurology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	Rationale for Removal: This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0101	318	139v6	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	Falls: Screening for Future Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences: Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g. advance directives, invasive ventilation, hospice) at least once annually	American Academy of Neurology	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.17. Mental/Behavioral Health

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Mental/Behavioral Health specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Mental/Behavioral Health specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measure from the specialty set: Quality ID: 367.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Opioid)	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Continuity of Pharmacotherapy for Opioid Use Disorder: Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment	University of Southern California
	0105	009	128v6	eCQM Specifications	Process	Effective Clinical Care	Anti-Depressant Medication Management: Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment. Two rates are reported: a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks) b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months)	National Committee for Quality Assurance
	0104	107	161v6	eCQM Specifications	Process	Effective Clinical Care	Adult Major Depressive Disorder (MDD): Suicide Risk Assessment: Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services

B.17. Mental/Behavioral Health (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specification s, eCQM Specification s, MIPS CQMs Specification s	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	2v7	Medicare Part B Claims Measure Specification s, eCQM Specification s, CMS Web Interface Measure Specification s, MIPS CQMs Specification s	Process	Community / Population Health	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specification s, MIPS CQMs Specification s	Process	Patient Safety	Elder Maltreatment Screen and Follow-Up Plan: Percentage of patients aged 65 years and older with a documented elder mal-treatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen	Centers for Medicare & Medicaid Services

B.17. Mental/Behavioral Health (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	2872	281	149v6	eCQM Specifications	Process	Effective Clinical Care	Dementia: Cognitive Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Dementia: Functional Status Assessment: Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association and American Academy of Neurology
	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Dementia: Associated Behavioral and Psychiatric Symptoms Screening and Management: Percentage of patients with dementia for whom there was a documented symptoms screening for behavioral and psychiatric symptoms, including depression, AND for whom, if symptoms screening was positive, there was also documentation of recommendations for symptoms management in the last 12 months.	American Psychiatric Association and American Academy of Neurology

B.17. Mental/Behavioral Health (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	<p>Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia: Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety screening * in two domains of risk: dangerousness to self or others and environmental risks; and if screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.</p> <p>Note: This measure title description have been updated since the NPRM due to inconsistencies between the measure tables.</p>	American Psychiatric Association and American Academy of Neurology
! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	<p>Dementia: Caregiver Education and Support: Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.</p>	American Psychiatric Association and American Academy of Neurology
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	<p>Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.</p>	Centers for Medicare & Medicaid Services

B.17. Mental/Behavioral Health (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	N/A	325	N/A	MIPS CQMs Specifications	Process	Communication/ Care Coordination	Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions: Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition	American Psychiatric Association
	0108	366	136v7	eCQM Specifications	Process	Effective Clinical Care	Follow-Up Care for Children Prescribed ADHD Medication (ADD): Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance

B.17. Mental/Behavioral Health (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* § ! (Outcome)	0710	370	159v6	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	Depression Remission at Twelve Months: The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
*	0712	371	160v6	eCQM Specifications	Process	Effective Clinical Care	Depression Utilization of the PHQ-9 Tool: The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period.	MN Community Measurement
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Safety)	1365	382	177v6	eCQM Specifications	Process	Patient Safety	Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment: Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	Adherence to Antipsychotic Medications for Individuals with Schizophrenia: Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months)	National Committee for Quality Assurance

B.17. Mental/Behavioral Health (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	0576	391	N/A	MIPS CQMs Specifications	Process	Communication/ Care Coordination	Follow-up After Hospitalization for Mental Illness (FUH): The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days of discharge • The percentage of discharges for which the patient received follow-up within 7 days of discharge	National Committee for Quality Assurance
	N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
* ! (Outcome)	0711	411	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Depression Remission at Six Months: The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission six months (+/- 60 days) after an index event date.	MN Community Measurement
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.17. Mental/Behavioral Health (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	367	169v6	eCQM Specifications	Process	Effective Clinical Care	Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use: Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use	Center for Quality Assessment and Improvement in Mental Health	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.18. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Diagnostic Radiology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Diagnostic Radiology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 359 and 363.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Radiology: Exposure Dose or Time Reported for Procedures Using Fluoroscopy: Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available)	American College of Radiology
! (Efficiency)	0508	146	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Radiology: Inappropriate Use of “Probably Benign” Assessment Category in Mammography Screening: Percentage of final reports for screening mammograms that are classified as “probably benign”	American College of Radiology
! (Care Coordination)	N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy: Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed	Society of Nuclear Medicine and Molecular Imaging
	0507	195	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Radiology: Stenosis Measurement in Carotid Imaging Reports: Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement	American College of Radiology

B.18. Diagnostic Radiology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0509	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	Radiology: Reminder System for Screening Mammograms: Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram	American College of Radiology
! (Patient Safety)	N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies: Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Patient Safety)	N/A	361	N/A	MIPS CQMs Specifications	Structure	Patient Safety	Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry: Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry that is capable of collecting at a minimum selected data elements	American College of Radiology

B.18. Diagnostic Radiology (continued)

MEASURES PROPOSED FOR **INCLUSION**

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	362	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes: Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study	American College of Radiology
* ! (Appropriate Use)	N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines: Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up [(e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians)]	American College of Radiology

B.18. Diagnostic Radiology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Appropriate Use)	N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Appropriate Follow-up Imaging for Incidental Abdominal Lesions: Percentage of final reports for abdominal imaging studies for asymptomatic patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended: • Liver lesion ≤ 0.5 cm • Cystic kidney lesion < 1.0 cm • Adrenal lesion ≤ 1.0 cm	American College of Radiology
! (Appropriate Use)	N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients: Percentage of final reports for computed tomography (CT), magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck or ultrasound of the neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended	American College of Radiology
	N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques: Percentage of final reports for patients aged 18 years and older undergoing CT with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control • Adjustment of the mA and/or kV according to patient size • Use of iterative reconstruction technique	American College of Radiology/American Medical Association-Physician Consortium for Performance Improvement/National Committee for Quality Assurance

B.18. Diagnostic Radiology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	359	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging: Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems.	American College of Radiology	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	363	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive: Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed	American College of Radiology	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.19. Nephrology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Nephrology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Nephrology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 122, 318, and 327.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	TBD	TBD	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	<p>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>	National Committee for Quality Assurance
	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	<p>Zoster (Shingles) Vaccination: The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.</p>	PPRNet
§ ! (Outcome)	0059	001	122v6	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications, eCQM Specifications	Intermediate Outcome	Effective Clinical Care	<p>Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%): Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.</p>	National Committee for Quality Assurance

B.19. Nephrology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ ! (Care Coordination) *	0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Medication Reconciliation Post-Discharge: The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age • Submission Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older	National Committee for Quality Assurance
	0041	110	147v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Care Coordination) *	0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Medication Reconciliation Post-Discharge: The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age • Submission Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older	National Committee for Quality Assurance

B.19. Nephrology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	0043	111	127v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Pneumococcal Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
§	0062	119	134v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Diabetes: Medical Attention for Nephropathy: The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period	National Committee for Quality Assurance
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Functional Outcome Assessment: Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies	Centers for Medicare & Medicaid Services

B.19. Nephrology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	1667	328	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL: Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.	Renal Physicians Association
!	N/A	330	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days: Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter	Renal Physicians Association
§	3059	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk: Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection	Physician Consortium for Performance Improvement
! (Patient Experience)	N/A	403	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Adult Kidney Disease: Referral to Hospice: Percentage of patients aged 18 years and older with a diagnosis of ESRD who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care	Renal Physicians Association

B.19. Nephrology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	122	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Adult Kidney Disease: Blood Pressure Management: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care	Renal Physicians Association	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
0101	318	139v6	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	Falls: Screening for Future Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”
N/A	327	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Pediatric Kidney Disease: Adequacy of Volume Management: Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist	Renal Physicians Association	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.20. General Surgery

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed General Surgery specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed General Surgery specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measure from the specialty set: Quality ID: 263.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Society of Plastic Surgeons
! (Patient Safety)	0239	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons
§ ! (Care Coordination) *	0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Medication Reconciliation Post-Discharge: The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age • Submission Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older	National Committee for Quality Assurance

B.20. General Surgery (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.20. General Surgery (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Sentinel Lymph Node Biopsy for Invasive Breast Cancer: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure	American Society of Breast Surgeons
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Unplanned Reoperation within the 30 Day Postoperative Period: Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period	American College of Surgeons
! (Outcome)	N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Unplanned Hospital Readmission within 30 Days of Principal Procedure: Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure	American College of Surgeons

B.20. General Surgery (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Surgical Site Infection (SSI): Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication: Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance

B.20. General Surgery (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	263	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Preoperative Diagnosis of Breast Cancer: The percent of patients undergoing breast cancer operations who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method	American Society of Breast Surgeons	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.21. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Vascular Surgery specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Vascular Surgery specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 257 and 423.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Society of Plastic Surgeons
! (Patient Safety)	0239	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services

B.21. Vascular Surgery (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specification s, eCQM Specification s, MIPS CQMs Specification s	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0028	226	138v6	Medicare Part B Claims Measure Specification s, eCQM Specification s, CMS Web Interface Measure Specification s, MIPS CQMs Specification s	Process	Community/ Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	165v6	Medicare Part B Claims Measure Specification s, eCQM Specification s, CMS Web Interface Measure Specification s, MIPS CQMs Specification s	Intermediate Outcome	Effective Clinical Care	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period	National Committee for Quality Assurance

B.21. Vascular Surgery (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Rate of Open Elective Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7): Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7)	Society for Vascular Surgeons
! (Outcome)	N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged at Home by Post-Operative Day #2): Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2)	Society for Vascular Surgeons
! (Outcome)	N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2): Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2)	Society for Vascular Surgeons
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.21. Vascular Surgery (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2): Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2	Society for Vascular Surgeons
! (Outcome)	1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive: Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive: Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	1534	347	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Who Are Discharged Alive: Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Surgical Site Infection (SSI): Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication: Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons

B.21. Vascular Surgery (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
! (Outcome)	1523	417	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Rate of Open Repair of Small or Moderate Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive: Percentage of patients undergoing open repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons
! (Outcome)	N/A	420	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Varicose Vein Treatment with Saphenous Ablation: Outcome Survey: Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology

B.21. Vascular Surgery (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	<p>Ischemic Vascular Disease All or None Outcome Measure (Optimal Control): The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include:</p> <ul style="list-style-type: none"> • Most recent blood pressure (BP) measurement is less than 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated • Statin Use Unless Contraindicated 	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.21. Vascular Surgery (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1519	257	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Statin Therapy at Discharge after Lower Extremity Bypass (LEB): Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge	Society for Vascular Surgeons	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0465	423	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Perioperative Anti-platelet Therapy for Patients Undergoing Carotid Endarterectomy: Percentage of patients undergoing carotid endarterectomy (CEA) who are taking an anti-platelet agent within 48 hours prior to surgery and are prescribed this medication at hospital discharge following surgery	Society for Vascular Surgeons	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.22. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Thoracic Surgery specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Thoracic Surgery specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 043 and 236.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Society of Plastic Surgeons
! (Patient Safety)	0239	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.22. Thoracic Surgery (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Outcome)	0129	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Prolonged Intubation: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours	American Thoracic Society
! (Outcome)	0130	165	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention	American Thoracic Society
! (Outcome)	0131	166	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Stroke: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours	American Thoracic Society

B.22. Thoracic Surgery (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	0114	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure: Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis	American Thoracic Society
! (Outcome)	0115	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason	Society of Thoracic Surgeons
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.22. Thoracic Surgery (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication: Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
§ !	0119	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG): Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure	Society of Thoracic Surgeons

B.22. Thoracic Surgery (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0134	043	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft.	Society of Thoracic Surgeons	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0018	236	165v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period	National Committee for Quality Assurance	We agree with specialty society feedback to remove this measure from this specialty set because blood pressure control is managed by care team members other than the cardiothoracic surgeon. Blood pressure outcomes are more likely attributed to the primary care provider or cardiologist. These eligible clinicians are part of the core treatment team that is responsible for the ongoing hypertension therapy.

B.23. Urology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Urology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Urology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measure from the specialty set: Quality ID: 048.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	TBD	TBD	eCQM Specifications, MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) change 6-12 months after diagnosis of Benign Prostatic Hyperplasia: Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6 to 12 months later with an improvement of 3 points.	Large Urology Group Practice Association In collaboration with Oregon Urology Institute
§ ! (Appropriate Use)	0389	102	129v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0390	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research
§	0062	119	134v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Diabetes: Medical Attention for Nephropathy: The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period	National Committee for Quality Assurance

B.23. Urology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
! (Patient Safety)	0239	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Urinary Incontinence: Assessment of Presence or Absence Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months	National Committee for Quality Assurance

B.23. Urology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	Centers for Medicare & Medicaid Services
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Biopsy Follow-Up: Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician	American Academy of Dermatology

B.23. Urology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication: Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence: Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per ACOG/AUGS/AUA guidelines.	American Urogynecologic Society
! (Patient Safety)	N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy: Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society

B.23. Urology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	2152	431	N/A	MIPS CQMs Specifications	Process	Community /Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user	Physician Consortium for Performance Improvement
! (Outcome)	N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair: Percentage of patients undergoing any surgery to repair pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 1 month after surgery	American Urogynecologic Society
! (Outcome)	N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair: Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 1 month after surgery	American Urogynecologic Society
! (Outcome)	N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	Proportion of Patients Sustaining a Ureter Injury at the Time of any Pelvic Organ Prolapse Repair: Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 1 month after surgery	American Urogynecologic Society
	N/A	462	645v1	eCQM Specifications	Process	Effective Clinical Care	Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy: Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.23. Urology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.24a. Oncology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Oncology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Oncology specialty set. This measure set does not have any measures that are proposed for removal from prior years.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Zoster (Shingles) Vaccination: The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0389	102	129v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0041	110	147v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.24a. Oncology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	0043	111	127v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Pneumococcal Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	0384	143	157v6	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	Oncology: Medical and Radiation – Pain Intensity Quantified: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	Oncology: Medical and Radiation – Plan of Care for Pain: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain	American Society of Clinical Oncology

B.24a. Oncology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Radical Prostatectomy Pathology Reporting: Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.24a. Oncology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Population/Community	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI)
§ ! (Appropriate Use)	1857	449	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies: Proportion of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies	American Society of Clinical Oncology
§ ! (Appropriate Use)	1858	450	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Trastuzumab Received By Patients With AJCC Stage I (T1c) –III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy: Proportion of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving trastuzumab	American Society of Clinical Oncology
§	1859	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	KRAS Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:: Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom KRAS gene mutation testing was performed.	American Society of Clinical Oncology

B.24a. Oncology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ ! (Patient Safety)	1860	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	Patients with Metastatic Colorectal Cancer and KRAS Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal: Antibodies: Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0210	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Proportion Receiving Chemotherapy in the Last 14 Days of life: Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0211	454	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Proportion of Patients who Died from Cancer with more than One Emergency Department Visit in the Last 30 Days of Life: Proportion of patients who died from cancer with more than one emergency room visit in the last 30 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0213	455	N/A	MIPS CQMs Specifications	Outcome	/ Effective Clinical Care	Proportion Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life: Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0215	456	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Proportion Not Admitted to Hospice: Proportion of patients who died from cancer not admitted to hospice.	American Society of Clinical Oncology
§ ! (Outcome)	0216	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Proportion Admitted to Hospice for less than 3 days: Proportion of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A	462	645v1	eCQM Specifications	Process	Effective Clinical Care	Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy: Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.24b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Radiation Oncology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Radiation Oncology specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measure from the specialty set: Quality ID: 156.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ ! (Appropriate Use)	0389	102	129v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Patient Experience)	0384	143	157v6	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	Oncology: Medical and Radiation – Pain Intensity Quantified: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	Oncology: Medical and Radiation – Plan of Care for Pain: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain	American Society of Clinical Oncology

B.24b. Radiation Oncology (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0382	156	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Oncology: Radiation Dose Limits to Normal Tissues: Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues	American Society for Radiation Oncology	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.25. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Infectious Disease specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Infectious Disease specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 065, 066, 091, 093, 116, 128, 176, 226, 275, 331, 332, 333, 334, 337, 387, 390, 394, 400, 401, and 447.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	TBD	TBD	eCQM Specifications	Process	Community/Population Health	HIV Screening: Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention
	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Zoster (Shingles) Vaccination: The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
	0041	110	147v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	0043	111	127v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Pneumococcal Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0409	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection	National Committee for Quality Assurance
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	HIV Viral Load Suppression: The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	HIV Medical Visit Frequency: Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
! (Appropriate Use)	N/A	407	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Appropriate Treatment of Methicillin-Sensitive Staphylococcus Aureus (MSSA) Bacteremia: Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. nafcillin, oxacillin or cefazolin) as definitive therapy.	Infectious Diseases Society of America

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0069	065	154v6	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Appropriate Treatment for Children with Upper Respiratory Infection (URI): Percentage of children 3 months-18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode	National Committee for Quality Assurance	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate treatment for children with upper respiratory infections, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	066	146v6	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Appropriate Testing for Children with Pharyngitis: Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate testing for children with pharyngitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Acute Otitis Externa (AOE): Topical Therapy: Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology-Head and Neck Surgery	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate topical therapy treatment for patients with acute otitis externa. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use: Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate topical therapy treatment for patients with acute otitis externa, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis: Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription	National Committee for Quality Assurance	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess the appropriate use of antibiotics for patients with acute bronchitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	<p>Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI \geq 18.5 and $<$ 25 kg/m²</p>	Centers for Medicare & Medicaid Services	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians as part of routine preventive care for patients. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Rheumatoid Arthritis (RA): Tuberculosis Screening: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).</p>	American College of Rheumatology	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by rheumatologists or other physicians as part of disease management for rheumatoid arthritis for patients. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians as part of preventive care for patients. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by gastroenterologists or other physicians as part of inflammatory bowel disease management. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse): Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms	American Academy of Otolaryngology-Head and Neck Surgery	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate treatment for patients diagnosed with acute sinusitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.

B.25. Infectious Disease (Continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate treatment for patients diagnosed with acute sinusitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, otolaryngologists, or other physicians to assess appropriate treatment for patients diagnosed with acute sinusitis. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	334	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier:</p> <p>Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test</p>	American Academy of Dermatology	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by dermatologists, rheumatologists, or other physicians to ensure appropriate testing prior to treatment with a biological immune response modifier. . Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:</p> <p>Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12 month reporting period</p>	Physician Consortium for Performance Improvement	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians as part of screening process for a high risk patient population. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	390	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.	American Gastroenterological Association	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, gastroenterologists, or other physicians to promote shared decision making with patient with hepatitis C. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
1407	394	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Immunizations for Adolescents: The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday	National Committee for Quality Assurance	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians as part of well child care for patients. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk: Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection	Physician Consortium for Performance Improvement Foundation (PCPI®)	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians to assess the appropriate screening for a high-risk patient population. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period	American Gastroenterological Association	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, gastroenterologists, or other physicians to ensure appropriate screening for patients with cirrhosis. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.

B.25. Infectious Disease (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	447	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Chlamydia Screening and Follow Up: The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in “Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years.”

B.26. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Neurosurgical specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Neurosurgical specialty set. This measure set does not have any measures that are proposed for removal from prior years.

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Experience)	2643	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	Average Change in Functional Status Following Lumbar Spine Fusion Surgery: For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative functional status to one year (nine to fifteen months) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.	Minnesota Community Measurement
! (Patient Experience)	N/A	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery: For patients age 18 and older undergoing lumbar discectomy laminotomy surgery, the average change from pre-operative functional status to three months (6 to 20 weeks) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.	Minnesota Community Measurement
! (Patient Experience)	N/A	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	Average Change in Leg Pain Following Lumbar Spine Fusion Surgery: For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative leg pain to one year (nine to fifteen months) post-operative leg pain using the Visual Analog Scale (VAS) patient reported outcome tool.	Minnesota Community Measurement
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Society of Plastic Surgeons

B.26. Neurosurgical (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0239	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Stroke and Stroke Rehabilitation: Thrombolytic Therapy: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV t-PA was initiated within three hours of time last known well	American Heart Association

B.26. Neurosurgical (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive: Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive: Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Clinical Outcome Post Endovascular Stroke Treatment: Percentage of patients with a mRS score of 0 to 2 at 90 days following endovascular stroke intervention	Society of Interventional Radiology
! (Outcome)	N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Door to Puncture Time for Endovascular Stroke Treatment: Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours	Society of Interventional Radiology
* ! (Outcome)	N/A	459	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	Average Change in Back Pain Following Lumbar Discectomy and/or Laminotomy: The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had lumbar discectomy laminotomy procedure	MN Community Measurement

B.26. Neurosurgical (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* ! (Outcome)	N/A	460	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	Average Change in Back Pain Following Lumbar Fusion: The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had lumbar spine fusion surgery	MN Community Measurement
* ! (Outcome)	N/A	461	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy: The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had lumbar discectomy laminotomy procedure	MN Community Measurement

B.27. Podiatry

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Podiatry specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Podiatry specialty set. In addition, as outlined at the end of this table, we are proposing to remove the following quality measures from the specialty set: Quality IDs: 154, 155, and 318.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	TBD	TBD	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	<p>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.</p>	American Podiatric Medical Association
	0416	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention- Evaluation of Footwear: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.</p>	American Podiatric Medical Association

B.27. Podiatry (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m ²	Centers for Medicare & Medicaid Services
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications MIPS CQMs Specifications	Process	Community /Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.27. Podiatry (continued)

MEASURES PROPOSED FOR REMOVAL

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."
0101	318	139v6	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	Falls: Screening for Future Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years."

B.28. Dentistry

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the Dentistry specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the Dentistry specialty set. This measure set does not have any measures that are proposed for removal from prior years.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A	378	75v6	eCQM Specifications	Outcome	Community/Population Health	Children Who Have Dental Decay or Cavities: Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period	Centers for Medicare & Medicaid Services
	N/A	379	74v7	eCQM Specifications	Process	Effective Clinical Care	Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists: Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome)	N/A	378	75v6	eCQM Specifications	Outcome	Community/Population Health	Children Who Have Dental Decay or Cavities: Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period	Centers for Medicare & Medicaid Services
	N/A	379	74v7	eCQM Specifications	Process	Effective Clinical Care	Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists: Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services

B.29. Rheumatology

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the Rheumatology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the Rheumatology specialty set. This measure set does not have any measures that are proposed for removal from prior years.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Care Coordination)	0045	024	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older: Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication	National Committee for Quality Assurance
	0046	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Screening for Osteoporosis for Women Aged 65-85 Years of Age: Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0041	110	147v7	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.29. Rheumatology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	0043	111	127v6	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Pneumococcal Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
* §	0421	128	69v6	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	68v7	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	Centers for Medicare & Medicaid Services
*	N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Tuberculosis Screening: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology

B.29. Rheumatology (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	N/A	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months.	American College of Rheumatology
	N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Functional Status Assessment: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months	American College of Rheumatology
	N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months	American College of Rheumatology
	N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Rheumatoid Arthritis (RA): Glucocorticoid Management: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months	American College of Rheumatology
§	0028	226	138v6	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.29. Rheumatology (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !! (Outcome)	0018	236	165v6	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period	National Committee for Quality Assurance
! (Patient Safety)	0022	238	156v6	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Use of High-Risk Medications in the Elderly: Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	N/A	317	22v6	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	50v6	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.30. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Physical Therapy/Occupational Therapy specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Physical Therapy/Occupational Therapy specialty set. This is a new specialty set for 2019; therefore, we are not proposing removal of any measures from this specialty set.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	TBD	TBD	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	<p>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>	National Committee for Quality Assurance
* §	0421	128	69v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	<p>Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter</p> <p>Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m²</p>	Centers for Medicare & Medicaid Services

B.30. Physical Therapy/Occupational Therapy (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	Centers for Medicare & Medicaid Services
! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Functional Outcome Assessment: Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies	Centers for Medicare & Medicaid Services
! (Outcome) *	0422	217	N/A	MIPS CQMs Specifications	Outcome	Communication and Care Coordination	Functional Status Change for Patients with Knee Impairments: A self-report measure of change in functional status for patients 14 year+ with knee impairments. The change in functional status (FS) assessed using FOTO's (knee) PROM (patient-reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality	Focus on Therapeutic Outcomes, Inc.

B.30. Physical Therapy/Occupational Therapy (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome) *	0423	218	N/A	MIPS CQMs Specifications	Outcome	Communication and Care Coordination	Functional Status Change for Patients with Hip Impairments: A self-report measure of change in functional status (FS) for patients 14 years+ with hip impairments. The change in functional status (FS) assessed using FOTO's (hip) PROM (patient-reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0424	219	N/A	MIPS CQMs Specifications	Outcome	Communication and Care Coordination	Functional Status Change for Patients with Foot or Ankle Impairments: A self-report measure of change in functional status (FS) for patients 14 years+ with foot and ankle impairments. The change in functional status (FS) assessed using FOTO's (foot and ankle) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0425	220	N/A	MIPS CQMs Specifications	Outcome	Communication and Care Coordination	Functional Status Change for Patients with Lumbar Impairments: A self-report outcome measure of change in functional status for patients 14 years+ with lumbar impairments. The change in functional status (FS) assessed using FOTO (lumbar) PROM (patient reported outcome measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality	Focus on Therapeutic Outcomes, Inc.

B.30. Physical Therapy/Occupational Therapy (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Outcome) *	0426	221	N/A	MIPS CQMs Specifications	Outcome	Communication and Care Coordination	Functional Status Change for Patients with Shoulder Impairments: A self-report outcome measure of change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in functional status (FS) assessed using FOTO's (shoulder) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0427	222	N/A	MIPS CQMs Specifications	Outcome	Communication and Care Coordination	Functional Status Change for Patients with Elbow, Wrist or Hand Impairments: A self-report outcome measure of functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS assessed using FOTO (elbow, wrist and hand) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0428	223	N/A	MIPS CQMs Specifications	Outcome	Communication and Care Coordination	Functional Status Change for Patients with Other General Orthopaedic Impairments: A self-report outcome measure of functional status (FS) for patients 14 years+ with general orthopaedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopaedic impairment). The change in FS assessed using FOTO (general orthopaedic) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality	Focus on Therapeutic Outcomes, Inc.

B.31. Geriatrics

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Geriatrics specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Geriatrics specialty set. This is a new specialty set for 2019; therefore, we are not proposing removal of any measures from this specialty set.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	TBD	TBD	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	<p>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	<p>Screening for Osteoporosis for Women Aged 65-85 Years of Age: Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis</p>	National Committee for Quality Assurance

B.31. Geriatrics (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ ! (Care Coordination) *	0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Medication Reconciliation Post-Discharge: The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is reported as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age • Submission Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months	National Committee for Quality Assurance
	0041	110	147v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement

B.31. Geriatrics (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	0043	111	127v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Pneumococcal Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include A.I.I. known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Elder Maltreatment Screen and Follow-Up Plan: Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen	Centers for Medicare & Medicaid Services
! (Patient Safety)	0022	238	156v6	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Use of High-Risk Medications in the Elderly: Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. 1) Percentage of patients who were ordered at least one high-risk medication. 2) Percentage of patients who were ordered at least two of the same high-risk medication	National Committee for Quality Assurance

B.31. Geriatrics (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	2872	281	149v6	eCQM Specifications	Process	Effective Clinical Care	Dementia: Cognitive Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period	Physician Consortium for Performance Improvement
	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Dementia: Functional Status Assessment: Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months	American Academy of Neurology
	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management: Percentage of patients with dementia for whom there was a documented symptoms screening for behavioral and psychiatric symptoms, including depression, AND for whom, if symptoms screening was positive, there was also documentation of recommendations for symptoms management in the last 12 months	American Academy of Neurology
! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	Dementia: Safety Concerns Screening and Mitigation Recommendations or Referral for Patients with Dementia: Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources or orders for home safety evaluation	American Academy of Neurology
! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Dementia: Caregiver Education and Support: Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months	American Academy of Neurology

B.31. Geriatrics (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* § ! (Outcome)	0710	370	159v6	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	Depression Remission at Twelve Months: The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Opioid Therapy Follow-up Evaluation: All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Documentation of Signed Opioid Treatment Agreement: All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Evaluation or Interview for Risk of Opioid Misuse: All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology
§ ! (Outcome)	0213	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	Proportion Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life: Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life	American Society of Clinical Oncology
	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community /Population Health	Zoster (Shingles) Vaccination: The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet

B.32. Urgent Care

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Urgent Care specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Urgent Care specialty set. This is a new specialty set for 2019; therefore, we are not proposing removal of any measures from this specialty set.

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Appropriate Use)	0069	065	154v6	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Appropriate Treatment for Children with Upper Respiratory Infection (URI): Percentage of children 3 months-18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode	National Committee for Quality Assurance
! (Appropriate Use)	N/A	066	146v6	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Appropriate Testing for Children with Pharyngitis: Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode	National Committee for Quality Assurance
! (Appropriate Use)	0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Acute Otitis Externa (AOE): Topical Therapy: Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNHF)
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use: Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNHF)
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis: The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription	National Committee for Quality Assurance

B.32. Urgent Care (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Patient Safety)	0419	130	68v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	Centers for Medicare & Medicaid Services
§	0028	226	138v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user	Physician Consortium for Performance Improvement
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated	Centers for Medicare & Medicaid Services

B.32. Urgent Care (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse): Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNHF)
! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNHF)
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNHF)
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance

B.32. Urgent Care (continued)

MEASURES PROPOSED FOR INCLUSION								
Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	2152	431	N/A	MIPS CQMs Specifications	Process	Community /Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user	Physician Consortium for Performance Improvement
! (Patient Safety)	0657	464	N/A	MIPS CQMs Specifications	Process	Patient Safety, Efficiency and Cost Reduction	Otitis Media with Effusion (OME): Systemic Antimicrobials-Avoidance of Inappropriate Use: Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNHF)

B.33. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B in this proposed rule, the proposed Skilled Nursing Facility specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. We seek comment on the measures available in the proposed Skill Nursing Facility specialty set. This is a new specialty set for 2019; therefore, we are not proposing removal of any measures from this specialty set.

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	TBD	TBD	Medicare Part B Claims Measure Specification, CMS Web Interface Measure Specification, MIPS CQMs Specification	Process	Patient Safety	<p>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months</p>	National Committee for Quality Assurance
§	0067	006	N/A	MIPS CQMs Specification	Process	Effective Clinical Care	<p>Coronary Artery Disease (CAD): Antiplatelet Therapy: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel</p>	American Heart Association
§	0070	007	145v6	eCQM Specification, MIPS CQMs Specification	Process	Effective Clinical Care	<p>Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI OR a current or prior LVEF <40% who were prescribed beta-blocker therapy</p>	Physician Consortium for Performance Improvement

B.33. Skilled Nursing Facility (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0083	008	144v6	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium For Performance Improvement
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan	National Committee for Quality Assurance
	0041	110	147v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement

B.33. Skilled Nursing Facility (continued)

MEASURES PROPOSED FOR INCLUSION

Indicator	NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy	American Heart Association
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Elder Maltreatment Screen and Follow-Up Plan: Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen	Centers for Medicare & Medicaid Services
	N/A	317	22v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated	Centers for Medicare & Medicaid Services
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy: Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA- approved anticoagulant drug for the prevention of thromboembolism during the measurement period	American College of Cardiology
	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Community /Population Health	Zoster (Shingles) Vaccination: The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination	PPRNet

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years

In this proposed rule, we are proposing to remove 34 previously finalized quality measures from the MIPS Program for the 2021 MIPS payment year and future years. These measures are discussed in detail below. As discussed in section III.H.3.h(2) of this proposed rule, please note that our measure removal criteria considers the following:

- Whether the removal of the measure impacts the number of measures available to a specific specialty
- Whether the measure addresses a priority area of the Meaningful Measures Initiative
- Whether the measure is linked closely to improved outcomes in patients

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in section III.H.3.h(2) of this proposed rule, we have made proposals this year on additional criteria that should be used for the removal of measures, such as: extreme topped out measures, which means measures that are topped-out with an average (mean) performance rate between 98-100%.

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0086	012	143v6	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPIF®)	We are proposing to remove this measure (finalized in (81 FR 77558 through 77675)) because it is duplicative in concept and patient population as the currently adopted Measure 141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care (finalized in 81 FR 77558 through 77675). Furthermore, Measure 012 neither assesses a clinical outcome nor one of the defined MIPS high priority areas. In addition, the measure's numerator is considered standard of care as it only captures assessment completion. Although this assessment is critical to determine if the patient's current course of treatment is therapeutic, Measure 141 not only captures that information, but also is more robust since it requires a reduction of IOP or plan of care. Accurate and precise IOP readings are imperative to evaluate a patient's risk of progressive optic nerve damage.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0088	018	167v6	eCQM Specifications	Process	Effective Clinical Care	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We are proposing to remove this measure (finalized in (81 FR 77558 through 77675)) because it is duplicative both in concept and patient population as the currently adopted Measure 019: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care (finalized in (81 FR 77558 through 77675)). Measure 019 is considered high priority because it promotes communication and care coordination with eligible clinicians managing diabetes care. The numerator of Measure 018 is considered the standard of care as it captures an assessment with no additional clinical action. Measure 018 neither assesses a clinical outcome nor one of the defined MIPS high priority areas.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0134	043	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft.	Society of Thoracic Surgeons	We are proposing to remove this measure (finalized in (81 FR 77558 through 77675)) because there is no longer variation in performance for the measure to be able to evaluate improvement in performance making this measure extremely topped-out as discussed in section III.H.3.h.(2) of this proposed rule. The average performance for this measure is 99% based on the current MIPS benchmarking data located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip . Therefore, we believe use of IMA has been widely accepted and implemented. The measure neither assesses a clinical outcome nor one of the defined MIPS high priority areas.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in (81 FR 77558 through 77675)) as a quality measure from the MIPS program because it is duplicative in concept and covers the same patient population as currently adopted Measure 050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (finalized in 81 FR 77558 through 77675). Measure 048 does not require a quality action (follow up, plan of care, etc.) that links to improved outcomes. The measure does not assess a clinical outcome nor one of the defined MIPS high priority areas. Measure 050 is a more robust measure that requires a quality action (plan of care) for the appropriate patient population.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0391	099	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade: Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade	College of American Pathologists	We propose the removal of this measure (finalized in (81 FR 77558 through 77675)) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.H.3.h.(2) of this proposed rule. The average performance for this measure is 99% based on the current MIPS benchmarking data located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip . In addition, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0392	100	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade: Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade	College of American Pathologists	We propose the removal of this measure (finalized in (81 FR 77558 through 77675)) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.H.3.h.(2) of this proposed rule. The average performance for this measure is 99.5% based on the current MIPS benchmarking data located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip . In addition, the measure neither assesses a clinical outcome nor one of the defined MIPS high priority areas.
N/A	122	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	Adult Kidney Disease: Blood Pressure Management: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR \geq 140/90 mmHg with a documented plan of care	Renal Physicians Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because the measure has neither been updated nor planned to be updated by the measure steward to reflect the current clinical guidelines as indicated by the measure steward.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0566	140	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement: Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) or their caregiver(s) who were counseled within 12 months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for preventing progression of AMD.	American Academy of Ophthalmology	We propose the removal of this measure (finalized in (81 FR 77558 through 77675)) because the measure neither assesses a clinical outcome nor one of the defined MIPS high priority areas. The measure's quality action that only requires the provision of counseling of AREDS risk factors, but does not require discontinuation of AREDS if risks/adverse effects are identified.
0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Preventable Healthcare Harm/ Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because we are proposing a new combined Falls measure (based on specifications in NQF 0101) that will include strata components for Future Falls Risk, Falls Risk Assessment, and Falls Risk Plan of Care. We refer readers to Table A.10 where this proposal is discussed.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because we are proposing a new combined Falls measure (based on specifications in NQF 0101) that will include strata components for Future Falls Risk, Falls Risk Assessment, and Falls Risk Plan of Care. We refer readers to Table A.10 where this proposal is discussed.
0382	156	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	Oncology: Radiation Dose Limits to Normal Tissues: Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues	American Society for Radiation Oncology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.H.3.h.(2) of this proposed rule. The average performance for this measure is 97.5% based on the current MIPS benchmarking data located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip .

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQT #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0056	163	123v6	eCQM Specifications	Process	Effective Clinical Care	<p>Comprehensive Diabetes Care: Foot Exam: The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.</p>	National Committee for Quality Assurance	<p>We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative to the currently adopted Measure 126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation (finalized in 81 FR 77558 through 77675). However, Measure 163 is designated as a core performance measure by the Core Quality Measures Collaborative (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html). Therefore, we specifically seek comments regarding the impact of removing this measure and replacing it with Measure 126. We strive to not duplicate measures in the program. We believe Measure 126 is a more appropriate measure because it targets an at-risk patient population, is clinically significant, and is in alignment with current clinical guidelines for neurological evaluation of diabetic neuropathy.</p>

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0659	185	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use: Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.H.3.h.(2) of this proposed rule. The average performance for this measure is 97.7% based on the current MIPS benchmarking data located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip . This measure is designated as a core performance measure by the Core Quality Measures Collaborative (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html). Therefore, we specifically seek comments regarding the impact of removing this measure.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0068	204	164v6	Medicare Part B Claims Measure Specifications, eQIM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet: Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it would be duplicative of the new proposed measure, "Ischemic Vascular Disease: Use of Aspirin or Antiplatelet Medication". We refer readers to Table A.7 where this measure is proposed. We strive to not duplicate measures in the program. We believe the proposed measure is more appropriate because it includes more appropriate denominator exceptions that allows for a more defined measure as it accounts for history of gastrointestinal bleeding, intracranial bleeding, bleeding disorder, allergy to aspirin or antiplatelets or use of non-steroidal anti-inflammatory agents. However, Measure 204 is designated as a core performance measure by the Core Quality Measures Collaborative (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html). Therefore, we specifically seek comments regarding the impact of removing this measure and replacing it with the new proposed measure, "Ischemic Vascular Disease: Use of Aspirin or Antiplatelet Medication."

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0562	224	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	Melanoma: Overutilization of Imaging Studies in Melanoma: Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.	American Academy of Dermatology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.H.3.h.(2) of this proposed rule. The average performance for this measure is 99.5% based on the current MIPS benchmarking data located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip .
1855	251	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Effective Clinical Care	Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients: This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the current ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer	College of American Pathologists	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.H.3.h.(2) of this proposed rule. The average performance for this measure is 99% based on the current MIPS benchmarking data located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip . In addition, the measure does not assess a clinical outcome or one of the defined MIPS high priority areas.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1519	257	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Statin Therapy at Discharge after Lower Extremity Bypass (LEB): Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge	Society for Vascular Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because the clinical concept is captured within currently adopted Measure 438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (finalized in 81 FR 77558 through 77675). Measure 438 captures all patients that require statin therapy. Whereas Measure 257 only captures a subset of the patient population undergoing lower extremity bypass.
N/A	263	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Preoperative Diagnosis of Breast Cancer: The percent of patients undergoing breast cancer operations who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method	American Society of Breast Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.H.3.h.(2) of this proposed rule. The average performance for this measure is 99.3% based on the current MIPS benchmarking data located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip . In addition, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	276	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Sleep Apnea: Assessment of Sleep Symptoms: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness	American Academy of Sleep Medicine	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative to the currently adopted Measure 277: Sleep Apnea: Severity Assessment at Initial Diagnosis (finalized in 81 FR 77558 through 77675). Measure 276 only represents a quality action to assess for the sleep symptoms whereas Measure 277 includes the assessment along with the severity. This measure also lacks a quality action for positive assessments and does not indicate the use of a standardized tool. Also, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.
N/A	278	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Sleep Apnea: Positive Airway Pressure Therapy Prescribed: Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy	American Academy of Sleep Medicine	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative to currently adopted Measure 279: Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy (finalized in 81 FR 77558 through 77675). Measure 279 is more robust and requires assessment of adherence to the therapy. Measure 278 does not assess a clinical outcome nor one of the defined MIPS high priority areas.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0101	318	139v6	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	Falls: Screening for Future Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because we are proposing a new combined Falls measure (based on specifications in NQF 0101) that will include strata components for Future Falls Risk, Falls Risk Assessment, and Falls Risk Plan of Care.
N/A	327	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	Pediatric Kidney Disease: Adequacy of Volume Management: Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist	Renal Physicians Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes as it does not require a quality action if adequate volume management is not achieved. . In addition, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	334	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.H.3.h.(2) of this proposed rule. The average performance for this measure is 1.6% (inverse measure where a lower score is better performance) based on the current MIPS benchmarking data located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip .
N/A	359	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging: Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems.	American College of Radiology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative of the currently adopted Measure 361: Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry (finalized in 81 FR 77558 through 77675). The use of standardized nomenclature within this measure is intended to enable reporting to Dose Index Registries to allow comparison across radiology sites. This measure does not require the submission to a Dose Index Registry as indicated in Measure 361, but merely using standard nomenclature. We will continue to maintain Measure 361 that represents a more robust quality action to submit standardized data elements to a Dose Index Registry.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	363	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive: Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed	American College of Radiology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because the quality action does not completely attribute to the radiologist submitting the measure. Often, the CT studies are ordered and completed by referring providers without opportunity to complete the quality action by the radiologist. This allows their quality performance score to be impacted by other eligible clinicians. In addition, the measure does not require a quality action that links to improved outcomes when the search is completed prior to the study (i.e. comparison).
N/A	367	169v6	eCQM Specifications	Process	Effective Clinical Care	Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use: Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use	Center for Quality Assessment and Improvement in Mental Health	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because the measure does not require a quality action that links to improved outcomes when assessed positive for alcohol or chemical substance use. The measure does not assess a clinical outcome or one of the defined MIPS high priority areas.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	369	158v6	eCQM Specifications	Process	Effective Clinical Care	Pregnant women that had HBsAg testing: This measure identifies pregnant women who had an HBsAg (hepatitis B) test during their pregnancy.	OptumInsight	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because the measure steward is no longer maintaining the measure for continued utilization. Furthermore, the measure is evaluating a standard of care as this test would be part of the routine screening for women receiving prenatal care and does not evaluate for care with positive testing results.
N/A	373	65v7	eCQM Specifications	Intermediate Outcome	Effective Clinical Care	Hypertension: Improvement in Blood Pressure: Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because a similar clinical concept is represented in Measure 236. It is our goal to ensure duplicate measures are not included in the program. In addition, Measure 236 may apply to a larger eligible clinician cohort and offers expanded data submission methods that are not offered by Measure 373.
N/A	375	66v6	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Functional Status Assessment for Total Knee Replacement: Changes to the measure description: Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) who completed baseline and follow-up patient-reported and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it would be duplicative of the proposed measure, Average Change in Functional Status Following Total Knee Replacement Surgery. We refer readers to Table A.3 where this measure is proposed. The proposed measure is more robust as it measures the degree of functional improvement, rather than merely assessment completion.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences: Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g. advance directives, invasive ventilation, hospice) at least once annually	American Academy of Neurology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative in concept and the patient population would be included within the currently adopted Measure 46: Care Plan (finalized in 81 FR 77558 through 77675). Measure 46 includes all patients seen to determine if a care plan for end of life issues is documented.
0465	423	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	Perioperative Anti-platelet Therapy for Patients Undergoing Carotid Endarterectomy: Percentage of patients undergoing carotid endarterectomy (CEA) who are taking an anti-platelet agent within 48 hours prior to surgery and are prescribed this medication at hospital discharge following surgery	Society for Vascular Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because the clinical concept is captured within our proposed measure Ischemic Vascular Disease: Use of Aspirin or Anti-platelet Medication. We refer readers to Table A.7 where this measure is proposed. The proposed measure captures all ischemic vascular disease patients that should be receiving an aspirin or anti-platelet medication. Whereas, Measure 423 only captures a subset of the patient population undergoing carotid endarterectomy.

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years (continued)

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	426	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU): Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU or other non-ICU location in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.	American Society of Anesthesiologists	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.H.3.h. (2) of this proposed rule. The average performance for this measure is 97.7% based on the current MIPS benchmarking data located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip .
N/A	427	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU): Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member.	American Society of Anesthesiologists	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.H.3.h.(2) of this proposed rule. The average performance for this measure is 97.9% based on the current MIPS benchmarking data located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip .

TABLE C: Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS E-Measure ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	447	N/A	MIPS CQMs Specifications	Process	Community / Population Health	Chlamydia Screening and Follow-up: The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative of currently adopted Measure 310: Chlamydia Screening for Women (finalized in 81 FR 77558 through 77675). We strive to not duplicate in the program. This measure is designated as a core performance measure by the Core Quality Measures Collaborative (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html). Therefore, we specifically seek comments regarding the impact of removing this measure.

TABLE Group D: Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years

D.1. Medication Reconciliation Post-Discharge

Category	Description
NQF #:	0097
Quality#:	046
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	<p>The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record.</p> <p>This measure is reported as three rates stratified by age group:</p> <ul style="list-style-type: none"> • Submission Criteria 1: 18-64 years of age • Submission Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older
Substantive Change:	Modified collection type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	<p>We propose to remove the CMS Web Interface Measure Specifications collection type. This is a process measure, which promotes care coordination when transitioning from an inpatient facility to outpatient care. Removal of this measure from the CMS Web Interface supports our effort to move towards outcome and more meaningful measures within the CMS Web Interface. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements.</p>

D.2. Pneumococcal Vaccination Status for Older Adults

Category	Description
NQF #:	0043
Quality#:	111
CMS E-Measure ID:	CMS127v6
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine
Substantive Change:	Modified collection type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	<p>We propose to remove the CMS Web Interface Measure Specifications collection type. This measure has lost NQF endorsement and no longer reflects the current guidelines. A new measure is under development to reflect current guidelines and may be proposed in the future. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specification collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements. We encourage stakeholders to submit a replacement measure for future consideration that is in alignment with the most current clinical guidelines.</p>

D.3. Diabetes: Eye Exam

Category	Description
NQF #:	0055
Quality #:	117
CMS E-Measure ID:	CMS131v6
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period
Substantive Change:	Modified collection type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the CMS Web Interface Measure Specifications collection type. This measure evaluates a process in the care for the patient. Removal of this measure from the CMS Web Interface Measure Specifications supports our effort to move towards outcome and meaningful measures. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specification collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements

D.4. Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF #:	0421
Quality #:	128
CMS E-Measure ID:	CMS69v6
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI \geq 18.5 and $<$ 25 kg/m ² .
Substantive Change:	Modified collection type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications Updated the denominator exception logic: for the eCQM Specifications collection type to allow medical reasons for not obtaining the BMI.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	<p>We propose to remove the CMS Web Interface Measure Specifications collection type. This measure evaluates a process in the care for the patient. Removal of this measure from the CMS Web Interface Measure Specifications supports our effort to move towards outcome and meaningful measures. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specification collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements.</p> <p>We propose to update the denominator exception logic for the eCQM Specifications collection type to allow medical reasons for not obtaining the BMI. The Technical Expert Panel (TEP) convened by the measure steward recommended adding a medical reason as there could be valid medical reasons for not obtaining the BMI. We agree with the TEP to add a medical exception. There are valid medical reasons that may inhibit the eligible clinicians from obtaining a BMI. Specifically, CMS69v6 has denominator exceptions for medical reasons for not providing the follow-up plan. These exceptions are currently expressed as “Intervention, Order not done” and “Medication, Order not done”. The proposed updated measure, CMS69v7, adds an exception to remove patients from the denominator who have a medical reason for not having a BMI performed. This exception was added to account for patients for whom it may be physically difficult to conduct a BMI, such as patients who are unable to stand or for whom their weight exceeds scale limits. This update will provide eligible clinicians the opportunity to exclude patients when there is an appropriate medical reason documented.</p>

D.5. Oncology: Medical and Radiation – Plan of Care for Pain

Category	Description
NQF #:	0383
Quality #:	144
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain
Substantive Change:	<p>The new numerator is revised to read: Patients for whom a plan of care to address moderate to severe pain is documented on or before the date of the second visit with a clinician.</p> <p>Updated the denominator to clearly state that population for this measure would be limited to patients who had moderate to severe pain.</p> <p>The new denominator is revised to read: All patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having moderate to severe pain or All patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy.</p>
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	<p>We propose to modify the numerator to state that the plan of care for pain management should be documented in the first 2 visits (not at any point during the performance period). The current measure requires the plan of care to be documented at any time during the performance period.</p> <p>We propose to modify the denominator to clearly state that the population for this measure would be limited to patients who had moderate to severe pain.</p> <p>Pain severity continues to remain largely unaddressed, especially in those patients who have moderate/severe pain. The edits to this measures numerator would ensure that the oncologist documents a plan of care early, so as to ensure that patients who have moderate to severe pain know what pain management options are available to them earlier on when receiving chemotherapy and radiation, and can become engaged early on in their healthcare decisions. The update to the numerator is based on American Society of Clinical Oncology feedback on the measure by Quality Oncology Practice Initiative registry users who realize that the measure should focus on this to ensure quality of life via pain management is improved in cancer patients.</p>

D.6. Rheumatoid Arthritis (RA): Tuberculosis Screening

Category	Description
NQF #:	N/A
Quality #:	176
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD)
Substantive Change:	<p>The new description is revised to read: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).</p> <p>The new numerator is revised to read: Patients for whom a TB screening was performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic DMARD.</p>
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	<p>We propose to update to the numerator to require the TB screening 12 months prior to the first biologic treatment rather than 6 months as currently stated. The measure steward believes this measure should be more in line with the specifications found in a similar measure developed by the American College of Rheumatology (ACR) and endorsed by the National Quality Forum (NQF). In creating its version of this measure, the ACR conducted an extensive development and review process. The measure was built by a panel of rheumatology experts, in conjunction with the ACR, based on quality of care guidelines and broad reviews of relevant research. Upon completion, the measure was shared with thousands of rheumatology providers across the U.S. for public comment. Following the comment period, the measure was updated appropriately based on the feedback received, then rigorously tested to ensure reliability and validity. The proposed measure, along with the results of the testing, was submitted to the NQF for review and obtained trial endorsement. We typically prefer the use of NQF endorsed measures over measures that lack endorsement. However, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure revision from tuberculosis screening from 6 months to 12 months can be supported by evidence and is an important measure to ensure proper tuberculosis screening for rheumatoid arthritis patients.</p>

D.7. Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity

Category	Description
NQF #:	N/A
Quality #:	177
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months.
Substantive Change:	<p>The new numerator is revised to read: Patients with disease activity assessed by an ACR-endorsed rheumatoid arthritis disease activity measurement tool classified into one of the following categories: remission, low, moderate or high, at least $\geq 50\%$ of total number of outpatient RA encounters in the measurement year.</p> <p>The new definition is revised to read: Assessment and Classification of Disease Activity – Assesses if physicians are utilizing a standardized, systematic approach for evaluating the level of disease activity for each patient at least for $\geq 50\%$ of total number of outpatient RA encounters. The scales/instruments listed are the ACR-endorsed tools that should be used to define activity level and cut-off points:</p> <ul style="list-style-type: none"> -Clinical Disease Activity Index (CDAI) -Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein) (DAS-28) -Patient Activity Scale (PAS) -Patient Activity Score-II (PAS-II) -Routine Assessment of Patient Index Data with 3 measures (RAPID 3) -Simplified Disease Activity Index (SDAI) <p>A result of any kind qualifies for meeting numerator performance.</p>
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	<p>We propose to update the numerator to change the requirement to assess disease activity from once a year to "$\geq 50\%$ of encounters in the measurement year" and to change the use of any standardized tool to only use ACR-endorsed tools. Currently, the measure is only required to be submitted once per performance period. The current measure identifies tools that are available, but allows eligible clinicians to utilize tools not listed within the specification.</p> <p>The proposed changes add a considerable degree of specificity to quality measure 177 by 1) limiting options for disease activity measures to those that have been found to be valid through a rigorous ACR process, and 2) changing the frequency of assessment to include a majority of clinical encounters for RA, since this approach would be consistent with current guidelines regarding treating to a pre-specified target.</p> <p>The ACR developed recommendations for the use of RA disease activity measures in clinical practice. And after thorough evaluation of around 63 available measures, ACR recommends the following 6 measures: CDAI, DAS28 (ESR or CRP), PAS, PAS-II, RAPID-3, and SDAI as ACR-endorsed RA disease activity measures to be used in clinical practice. Many of these tools are available free of charge. The tools were selected to ensure a comprehensive and standardized approach to assess disease activity for rheumatoid arthritis.</p> <p>Given this evidence, the measure steward believes this measure should be updated to be more in line with the specifications found in similar measures developed by ACR and endorsed by NQF. We agree with the proposed revision to promote utilization of the most current guidelines that have been developed by the panel of rheumatology experts. We typically prefer the use of NQF endorsed measures over measures that lack endorsement. Disease activity assessment is imperative to development of an appropriate treatment plan. Revising the numerator to require a more frequent assessment supports development of a more effective treatment plan. We support the use of standardized tools to assess disease activity so the score can be standardized and comparable among eligible clinicians.</p>

D.8. Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines

Category	Description
NQF #:	N/A
Quality #:	364
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for computed tomography (CT) imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors.
Substantive Change:	<p>Updated the denominator: To patients 35 years and older.</p> <p>Updated denominator exclusions: Added heavy tobacco smokers</p> <p>Updated denominator exceptions: To include medical reasons.</p> <p>Updated numerator: Includes a recommended interval and modality for follow-up.</p> <p>The new description is revised to read: Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up [(e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians)]</p>
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	<p>We propose to update the measure description and denominator from 18 years and older to 35 years and older. We also propose to update the numerator to include a recommended interval and modality for follow-up. The revised measure assesses final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up [(e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians)]. The current measure specification does not allow a denominator exclusion for heavy smokers. A new denominator exclusion is included for heavy tobacco smokers who qualify for lung cancer screening. Furthermore, the current denominator exception does not account for the indication of a modality. A new denominator exception for medical reasons for not including a recommended interval and modality for follow-up.</p> <p>The proposed changes add specificity to this measure and ensure the appropriate patient population is being targeted for this measure by 1) updating the numerator quality action to specify a recommended interval and modality for follow-up, 2) specifying additional denominator exclusions and exceptions, and 3) changing the intended patient population (to 35 years and older) as supported by an update to clinical guidelines. We agree with the proposed revision to promote utilization of the most current guidelines. It creates a more robust measure that defines the required clinical action to the narrowed patient population. We also agree with the addition specific denominator exceptions and denominator exclusions to promote consistent data among eligible clinicians.</p>

D.9. Depression Remission at Twelve Months

Category	Description
NQF #:	0710
Quality #:	370
CMS E-Measure ID:	CMS159v6
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eQOM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18 years of age and or older with major depression or dysthymia who reached remission 12 months (+/- 30 days) after an index visit
Substantive Change:	<p>The new description is revised to read: The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.</p> <p>The new denominator is revised to read: Adolescent patients 12 to 17 years of age with a diagnosis of major depression or dysthymia and an initial PHQ-9 or PHQ-9M score greater than nine during the index event.</p> <p>The new numerator is revised to read: Adolescent patients aged 12 to 17 years of age who achieved remission at twelve months as demonstrated by a twelve month (+/- 60 days) PHQ-9 or PHQ-9M score of less than five</p>
Steward:	Minnesota Community Measurement (MNCM)
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	<p>We propose to add adolescents to the denominator via stratification and references to the PHQ-9M, which is specific for adolescents. The patient population has been revised to include patients 12 years of age and older, when previously only included patients over the age of eighteen. The score to determine denominator eligibility was based on the PHQ-9 assessment, this was expanded to include the PHQ-9M to accommodate the expanded age with age appropriate assessment tools. The measure steward worked in collaboration with NCQA, who requested a consideration of incorporating adolescents into the existing depression measures. We agree with the expansion of the denominator to include the adolescent patient population. Depression assessment is a clinically relevant and important topic to address among adolescents. We appreciate the collaboration among the stakeholders to broaden the measure.</p>

D.10. Depression Utilization of the PHQ-9 Tool

Category	Description
NQF #:	0712
Quality #:	371
CMS E-Measure ID:	CMS160v6
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCOM Specifications
Current Measure Description:	The percentage of patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying visit
Substantive Change:	<p>The new description is revised to read: The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period.</p> <p>The new denominator is revised to read: Adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia.</p> <p>The new numerator is revised to read: Adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) included in the denominator who have at least one PHQ-9 or PHQ-9M tool administered and completed during a four month measurement period.</p>
Steward:	Minnesota Community Measurement (MNCM)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add adolescents to the denominator via stratification and references to the PHQ-9M for both denominator and numerator, which is specific for adolescents. The patient population has been revised to include patients 12 years of age and older, when previously only included patients over the age of eighteen. The measure steward worked in collaboration with NCQA, who requested a consideration of incorporating adolescents into the existing depression measures. We agree with the expansion of the denominator to include the adolescent patient population. Depression assessment is a clinically relevant and important topic to address among adolescents. We appreciate the collaboration among the stakeholders to broaden the measure.

D.11. Melanoma Reporting

Category	Description
NQF #:	N/A
Quality #:	397
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate.
Substantive Change:	The new numerator is revised to read: Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate.
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the numerator to include mitotic rate for all pT categories. The current measure specification only requires a statement the mitotic rate for pT1. The American Joint Committee on Cancer's Melanoma Expert Panel strongly recommends that mitotic rate be assessed and recorded for all primary melanomas, although it is not used for T1 staging in the eighth edition. The mitotic rate will likely be an important parameter for inclusion in the future development of prognostic models applicable to individual patients. Although it is not included in the T1 subcategory criteria, mitotic activity in T1 melanomas also has been associated with an increased risk of sentinel lymph node metastasis. We agree with the addition of mitotic rate assessment for all primary melanomas. This creates valuable clinical information to the eligible clinician in order to create an effective treatment plan specific to the melanoma.

D.12. Psoriasis: Clinical Response to Oral Systemic or Biologic Medications

Category	Description
NQF #:	N/A
Quality #:	410
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of psoriasis vulgaris patients receiving oral systemic or biologic therapy who meet minimal physician-or patient-reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.
Substantive Change:	<p>The new description is revised to read: Percentage of psoriasis vulgaris patients receiving systemic therapy who meet minimal physician-or patient-reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment</p> <p>The new denominator is revised to read: All patients with a diagnosis of psoriasis vulgaris and treated with a systemic medication.</p> <p>The new numerator is revised to read: Patients who have a documented physician global assessment (PGA; 5-point OR 6-point scale), body surface area (BSA), psoriasis area and severity index (PASI) and/or dermatology life quality index (DLQI) that meet any one of the below specified benchmarks.</p>
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	<p>We propose to update the measure title, description and denominator to expand the measure to include systemic medications that are administered both orally and subcutaneously. The measure still includes biologics rather than only oral and biologic medications. The patient population includes those diagnosed with psoriasis vulgaris receiving systemic medications that are administered both orally and subcutaneously or biologic therapy who meet minimal physician-or patient-reported disease activity levels. In addition, the numerator is being expanded to include the 5-point PGA scale as an additional benchmark. The current numerator allow the use of PGA; 6-point scale), body surface area (BSA), psoriasis area and severity index (PASI) and/or dermatology life quality index (DLQI) to assess clinical response.</p> <p>The measure steward believes the update to allow all systemic medications is relevant as they have deemed them to all apply to the measure. Based on recent literature, there is a strong correlation in how the 5-point scale is used like the 6-point PGA scale, resulting in comparative results. This scale is requested to be added to allow clinicians a shorter scale to choose from which would be more user-friendly in a clinical setting. We agree with the expansion of the denominator to include all systemic medications, not limited to oral systemic or biologic therapy. Including systemic medications administered subcutaneously provides an additional opportunity to assess effective outcomes this treatment option. We agree with the 5-point PGA scale to allow an additional tools to assess psoriasis outcomes.</p>

D.13. Depression Remission at Six Months

Category	Description
NQF #:	0711
Quality #:	411
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18 years of age or older with major depression or dysthymia who reached remission six months (+/- 30 days) after an index visit.
Substantive Change:	<p>The new description is revised to read: The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission six months (+/- 60 days) after an index event date.</p> <p>The new denominator is revised to read: Adolescent patients 12 to 17 years of age with a diagnosis of major depression or dysthymia and an initial PHQ-9 or PHQ-9M score greater than nine during the index event.</p> <p>The new description is revised to read: Adolescent patients aged 12 to 17 years of age who achieved remission at six months as demonstrated by a six month (+/- 60 days) PHQ-9 or PHQ-9M score of less than five.</p>
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	<p>We propose to add adolescents to denominator via stratification and references to the PHQ-9M which is specific for adolescents. The patient population has been revised to include patients 12 years of age and older, when previously only included patients over the age of eighteen. The score to determine denominator eligibility was based on the PHQ-9 assessment, this was expanded to include the PHQ-9M to accommodate the expanded age with age appropriate assessment tools. The measure steward worked in collaboration with NCQA, who requested a consideration of incorporating adolescents into the existing depression measures. We agree with the expansion of the denominator to include the adolescent patient population. Depression assessment is a clinically relevant and important topic to address among adolescents. We appreciate the collaboration among the stakeholders to broaden the measure.</p>

D.14. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older

Category	Description
NQF #:	N/A
Quality #:	415
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT
Substantive Change:	<p>Updated the measure description and denominator to remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15.</p> <p>The new description is revised to read: Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.</p> <p>The new denominator is revised to read: All emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider</p> <p>Updated the numerator: To indicate the GCS score less than 15 is an appropriate indication for a head CT.</p> <p>The new definition within the numerator is revised to include a GSC score less than 15.</p>
Steward:	American College of Emergency Physicians (ACEP)
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	<p>We propose to update to the measure description and denominator to remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15. We propose to update the numerator to indicate the GCS score less than 15 is an appropriate indication for a head CT. The new description is revised to read: Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.</p> <p>Based on feedback from the measure steward, this measure is appropriate for all minor blunt head traumas, regardless of when they occurred in relation to presentation to the ED. Additionally, in order to better align the measure with the evidence base and guidelines supporting the measure, the measure steward determined that the GCS of <15 data element would be more accurately included as an appropriate indication for ordering a head CT, so this has been relocated to the numerator definition. We agree with the recommendation and propose the revision as this promotes utilization of the most current guidelines to determine imaging requirements based on the documented GCS.</p>

D.15. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years

Category	Description
NQF #:	N/A
Quality #:	416
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury
Substantive Change:	<p>Updated denominator: To remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15.</p> <p>The measure description is revised to read: Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.</p> <p>Updated the numerator: To indicate the GCS score less than 15 is an appropriate indication for a head CT.</p>
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	<p>We propose to update the measure description and denominator to remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15. We propose to update the numerator to indicate the GCS score less than 15 is an appropriate indication for a head CT.</p> <p>Based on feedback from the measure steward, this measure is appropriate for all minor blunt head traumas, regardless of when they occurred in relation to presentation to the ED. Additionally, in order to better align the measure with the evidence base and guidelines supporting the measure, ACEP physician leaders determined that the GCS of <15 data element would be more accurately included as an appropriate indication for ordering a head CT, so this has been relocated to the numerator definition. We agree with the proposed revision as this promotes utilization of the most current guidelines to determine imaging requirement based on the documented GCS.</p>

D.16. Functional Status Change for Patients with Knee Impairments

Category	Description
NQF #:	0422
Quality #:	217
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report measure of change in functional status for patients 14 year+ with knee impairments. The change in functional status (FS) assessed using FOTO's (knee) PROM (patient-reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. The new denominator is revised to expand to: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to expand the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agree with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

D.17. Functional Status Change for Patients with Hip Impairments

Category	Description
NQF #:	0423
Quality #:	218
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report measure of change in functional status (FS) for patients 14 years+ with hip impairments. The change in functional status (FS) assessed using FOTO's (hip) PROM (patient-reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. The new denominator is revised to expand to: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to expand the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agree with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

D.18. Functional Status Change for Patients with Foot or Ankle Impairments

Category	Description
NQF #:	0424
Quality #:	219
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report measure of change in functional status (FS) for patients 14 years+ with foot and ankle impairments. The change in functional status (FS) assessed using FOTO's (foot and ankle) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. The new denominator is revised to expand to: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to expand the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agree with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

D.19. Functional Status Change for Patients with Lumbar Impairments

Category	Description
NQF #:	0425
Quality #:	220
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of change in functional status for patients 14 years+ with lumbar impairments. The change in functional status (FS) assessed using FOTO (lumbar) PROM (patient reported outcome measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. The new denominator is revised to expand to: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to expand the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agree with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

D.20. Functional Status Change for Patients with Shoulder Impairments

Category	Description
NQF #:	0426
Quality #:	221
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in functional status (FS) assessed using FOTO's (shoulder) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. The new denominator is revised to expand to: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to expand the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agree with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

D.21. Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
NQF #:	0427
Quality #:	222
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS assessed using FOTO (elbow, wrist and hand) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. The new denominator is revised to expand to: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to expand the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agree with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

D.22. Functional Status Change for Patients with General Orthopaedic Impairments

Category	Description
NQF #:	0428
Quality #:	223
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of functional status (FS) for patients 14 years+ with general orthopaedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopaedic impairment). The change in FS assessed using FOTO (general orthopaedic) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. The new denominator is revised to expand to: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to expand the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agree with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

D.23. Overuse Of Imaging For Patients With Primary Headache

Category	Description
NQF #:	N/A
Quality #:	419
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with a diagnosis of primary headache disorder whom advanced brain imaging was not ordered
Substantive Change:	<p>Updated the measure analytics to be an inverse measure and remove the assessment of the appropriate use for Computed Tomography Angiography (CTA) and Magnetic Resonance Angiography (MRA).</p> <p>The new description is revised to read: Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present</p> <p>The new numerator is revised to: Patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.</p>
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We propose to adjust the measure analytics to produce inverse performance data and update the numerator to reflect new clinical evidence regarding the diagnostic imaging modalities (removing CTA and MRA). Updating inverse measure analytics for this measure will appropriately represent the data produced by an overuse measure. The measure development workgroup, procured by AAN, reviewed available evidence and found that there are different indications for imaging with CTA and MRA compared to CT and MRI. The indications for clinical management of primary headache, (which are listed in the measure) are only appropriate for CT and MRI. The updated clinical guidelines included in the measure support this as well.

Appendix 2: Improvement Activities

For previously finalized improvement activities, we refer readers to the finalized Improvement Activities Inventory in Table F in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175) and in Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77818). Unless modified or removed in the CY 2019 Physician Fee Schedule final rule, previously finalized improvement activities continue to apply for the MIPS CY 2019 performance period and future years.

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53569) for our most recently adopted criteria for nominating new improvement activities. We refer readers to section III.H.3.h.(4)(d)(i) of this proposed rule, for information regarding our proposals to add one new criterion and remove a previously adopted criterion. In addition, we refer readers to section III.H.3.h.(4)(d)(i) of this proposed rule where we are also making clarifications to: (1) considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities. Below, we are proposing six (6) new improvement activities; we are also proposing to modify five (5) existing activities and remove one (1) existing activity for CY 2019 performance period and future years.

TABLE A: Proposed New Improvement Activities for the MIPS CY 2019 Performance Period and Future Years

Proposed Improvement Activity	
Proposed Activity ID:	IA_AHE_XX
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Comprehensive Eye Exams
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by providing literature and/or facilitating a conversation about this topic using resources such as the “Think About Your Eyes” campaign ⁷² and/or referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology’s EyeCare America ⁷³ and the American Optometric Association’s VISION USA ⁷⁴ . This activity is intended for: (1) non-ophthalmologists / optometrist who refer patients to an ophthalmologist/optometrist; (2) ophthalmologists/optometrists caring for underserved patients at no cost; or (3) any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams.
Proposed Weighting:	Medium
Rationale	<p>This activity fills a gap as the Inventory does not currently contain an activity related to ophthalmology. Furthermore, we believe promoting and educating patients about the importance of a comprehensive eye exam can improve access to this service and, in turn, improve health status particularly for traditionally underserved populations or to those who are otherwise unable to access these important services. For these reasons, we believe this activity meets the inclusion criteria of an activity that could lead to improvement in practice to reduce health care disparities.</p> <p>We are proposing the weighting of this activity as medium because this activity may be accomplished by providing literature and/or facilitating a conversation with a patient during a regular visit. This task may be incorporated into a patient’s</p>

⁷² The Think About Your Eyes resource may be found at <http://thinkaboutyoureyes.com>.

⁷³ The American Academy of Ophthalmology’s EyeCare America resource may be found at <https://www.aao.org/eyecare-america>.

⁷⁴ The American Optometric Association’s VISION USA resource may be found at <http://www.aoafoundation.org/vision-usa/>.

	regular visit with a relatively low investment of time or resources.
Proposed Improvement Activity	
Proposed Activity ID:	IA_BE_XX
Proposed Subcategory:	Beneficiary Engagement
Proposed Activity Title:	Financial Navigation Program
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must attest that their practice provides financial counseling to patients or their caregiver about costs of care and an exploration of different payment options. The MIPS eligible clinician may accomplish this by working with other members of their practice (for example, financial counselor or patient navigator) as part of a team-based care approach in which members of the patient care team collaborate to support patient-centered goals. For example, a financial counselor could provide patients with resources with further information or support options, or facilitate a conversation with a patient or caregiver that could address concerns. This activity may occur during diagnosis stage, before treatment, during treatment, and/or during survivorship planning, as appropriate.
Proposed Weighting:	Medium
Rationale:	<p>We believe there is the possibility for improved outcomes when financial navigation programs are in place, such as reducing patient anxiety about costs and improved access to care for underserved populations. For these reasons, we believe this activity meets the inclusion criteria of an activity that could lead to improvement in practice to reduce health care disparities.</p> <p>We are proposing the weighting of this activity as medium because the activity may be accomplished by providing literature and/or facilitating a conversation with a patient during a regular visit. This task may be incorporated into a patient's regular visit with a relatively low investment of time or resources.</p>
Proposed Improvement Activity	
Proposed Activity ID:	IA_BMH_XX
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Completion of Collaborative Care Management Training Program
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychological Association (APA) Collaborative Care Model training program available as part of the Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI) ⁷⁵ , available to the public ⁷⁶ , in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Proposed Weighting:	Medium
Rationale:	Collaborative care management approaches to integrating behavioral health into primary care practice have been associated with significant improvements in mental health symptom acuity and adherence to treatment in the short- to mid-term ^{77,78,79} . In addition, this activity meets the inclusion criteria of an activity that is likely to lead to improved beneficiary health outcomes.

⁷⁵ Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI) information may be found at <https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/>.

⁷⁶ American Psychological Association (APA) Collaborative Care Model training program information may be found at <https://www.psychiatry.org/psychiatrists/practice/professional-interests/integrated-care/get-trained>.

⁷⁷ Angstman, K. B., Meunier, M. R., Rohrer, J. E., Oberhelman, S. S., Maxson, J. A., & Rahman, P. A. (2014). Future complexity of care tier affected by depression outcomes. *J Prim Care Community Health*, 5(1), 30-35. doi: 10.1177/2150131913511465.

⁷⁸ Archer, J., Bower, P., Gilbody, S., Lovell, K., Richards, D., Gask, L., Coventry, P. (2012). Collaborative care for depression and anxiety problems. *Cochrane Database of Systematic Reviews*, 10.

	We are proposing the weighting of this activity as medium because participation in a training program consists of online reading, attending webinars, or other one-time or short-term activities, which, though beneficial, do not require substantial time or effort by clinicians.
Proposed Improvement Activity	
Proposed Activity ID:	IA_CC_XX
Proposed Subcategory:	Care Coordination
Proposed Activity Title:	Relationship-Centered Communication
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must participate in a minimum of eight hours of training on relationship-centered care ⁸⁰ tenets such as making effective open-ended inquiries; eliciting patient stories and perspectives; listening and responding with empathy; using the ART (ask, respond, tell) communication technique to engage patients, and developing a shared care plan. The training may be conducted in formats such as, but not limited to: interactive simulations practicing the skills above, or didactic instructions on how to implement improvement action plans, monitor progress, and promote stability around improved clinician communication.
Proposed Weighting:	Medium
Rationale:	There is currently not an activity in the Inventory that addresses communication between patients and clinicians; this proposed activity would help fill a gap. We believe that this proposed activity meets the inclusion criteria of an activity that is likely to lead to improved beneficiary health outcomes based on research citing the importance of relationship-centered care to patient safety ⁸¹ . We are proposing the weighting of this activity as medium because participation in an eight hour training on relationship-centered care, though beneficial, does not require substantial time or effort by clinicians
Proposed Improvement Activity	
Proposed Activity ID:	IA_PSPA_XX
Proposed Subcategory:	Patient Safety and Practice Assessment
Proposed Activity Title:	Patient Medication Risk Education
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must provide both written and verbal education regarding the risks of concurrent opioid and benzodiazepine use for patients who are prescribed both benzodiazepines and opioids. Education must be completed for at least 75% of qualifying patients and occur: (1) at the time of initial co-prescribing and again following greater than 6 months of co-prescribing of benzodiazepines and opioids, or (2) at least once per MIPS performance period for patients taking concurrent opioid and benzodiazepine therapy.
Proposed Weighting:	High
Rationale:	This activity addresses the Meaningful Measures priority area of Prevention and Treatment of Opioid and Substance Use Disorders ⁸² and addresses the role of clinicians in management of concurrent prescriptions, a topic that is not currently represented in the Inventory. We believe this activity meets the inclusion criteria of

⁷⁹ Recommendation from the Community Preventive Services Task Force for Use of Collaborative Care for the Management of Depressive Disorders. Am J Prev Med (2012), 42(5), 521-524.

⁸⁰ Nundy, S. and J. Oswald (2014). "Relationship-centered care: A new paradigm for population health management." Healthcare 2(4): 216-219.

⁸¹ Dingley, C., Daugherty, K., Derieg, M. K., & Persing, R. (2008). Advances in Patient Safety: Improving Patient Safety through Provider Communication Strategy Enhancements. In: Henriksen K, Battles JB, Keyes MA, et al., editors. Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 3: Performance and Tools). Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Aug. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK43663/>.

⁸² Meaningful Measures Framework information may be found at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

	<p>an activity that is likely to lead to improved beneficiary health outcomes due to the prevalence of opioid and substance abuse disorders and the medical consequences of mismanagement of concurrent benzodiazepine and opioid prescription⁸³.</p> <p>We are proposing the weighting of this activity as high because it addresses a public health emergency⁸⁴ and may reduce preventable health conditions related to opioid abuse. High weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being, as explained in the CY 2017 Quality Payment Program final rule (81 FR 77194). We also refer readers to our clarifications regarding weighting at section III.H.3.h.(4) of this proposed rule. According to the CDC, about 63,000 people died in 2016 of a drug overdose, and well over half of them are attributed to opioids.⁸⁵ According to the 2016 National Survey on Drug Use and Health (NSDUH), 11.8 million individuals ages 12 and older misused any opioid (that is, prescription and/or illicit opioids) and 11.5 million individuals misused prescription opioids. Of those who misused opioids, 2.1 million individuals meet the criteria for an opioid use disorder.⁸⁶ Since providing education regarding the risks of concurrent opioid and benzodiazepine use directly addresses the opioid epidemic, we believe this improvement activity meets our considerations for high-weighting.</p>
Proposed Improvement Activity	
Proposed Activity ID:	IA_PSPA_XX
Proposed Subcategory:	Patient Safety and Practice Assessment
Proposed Activity Title:	Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must utilize the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain ⁸⁷ via clinical decision support (CDS). For CDS to be most effective, it needs to be built directly into the clinician workflow and support decision making on a specific patient at the point of care. Specific examples of how the guideline could be incorporated into a CDS workflow include, but are not limited to: electronic health record (EHR)-based prescribing prompts, order sets that require review of guidelines before prescriptions can be entered, and prompts requiring review of guidelines before a subsequent action can be taken in the record.
Proposed Weighting:	High
Rationale:	This activity addresses the Meaningful Measures priority areas of Prevention and Treatment of Opioid and Substance Use Disorders and Transfer of Health Information and Interoperability ⁸⁸ . Electronic tools like CDS can assist clinicians

⁸³ McClure, F. L., Niles, J. K., Kaufman, H. W., & Gudin, J. (2017). Concurrent Use of Opioids and Benzodiazepines: Evaluation of Prescription Drug Monitoring by a United States Laboratory. *Journal of Addiction Medicine*, 11(6), 420–426. <http://doi.org/10.1097/ADM.0000000000000354>.

⁸⁴ Department of Health and Human Services. (2018) "HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis" Available at <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html>.

⁸⁵ Hedegaard, H., Warner, M., & Miniño, A. M. (2017). NCHS Data Brief No. 294. Center for Disease Control and Prevention National Center for Health Statistics. Available at <https://www.cdc.gov/nchs/products/databriefs/db294.htm>.

⁸⁶ Park-Lee, E., Lipari, R. N., Hedden, S. L., Kroutil, L. A., & Porter, J. D. (2017). Receipt of Services for Substance Use and Mental Health Issues among Adults: Results from the 2016 National Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration NSDUH Data Review. Available at <https://www.samhsa.gov/data/sites/default/files/NSDUH-DR-FFR2-2016/NSDUH-DR-FFR2-2016.htm>.

⁸⁷ CDC Prescribing Guidelines resource may be found at <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

⁸⁸ Centers for Medicare & Medicaid "Meaningful Measures Framework" resource may be found at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

	<p>in preventing adverse patient outcomes. We believe this activity meets the inclusion criteria of an activity that is likely to lead to improved beneficiary health outcomes due to the prevalence of opioid and substance abuse disorders and evidence of CDS supporting improved outcomes and patient safety⁸⁹.</p> <p>We are proposing the weighting of this activity as high because it promotes interoperability and addresses a public health emergency and may reduce preventable health conditions related to opioid abuse. High weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being, as explained in the CY 2017 Quality Payment Program final rule (81 FR 77194). We also refer readers to our clarifications regarding weighting at section III.H.3.h.(4) of this proposed rule. According to the CDC, about 63,000 people died in 2016 of a drug overdose, and well over half of them are attributed to opioids.⁹⁰ According to the 2016 National Survey on Drug Use and Health (NSDUH), 11.8 million individuals ages 12 and older misused any opioid (that is, prescription and/or illicit opioid) and 11.5 million individuals misused prescription opioids. Of those who misused opioids, 2.1 million individuals meet the criteria for an opioid use disorder.⁹¹ Since providing education regarding the risks of concurrent opioid and benzodiazepine use directly helps to address the opioid epidemic, and use of CDS addresses CMS's policy focus on promoting interoperability⁹² we believe this improvement activity meets our considerations for high-weighting.</p>
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We solicit public comment on our proposals to adopt the improvement activities as discussed in Table A in the Improvement Activities Inventory for the MIPS CY 2019 performance period and future years.

⁸⁹ Hummel, J. Office of the National Coordinator for Health Information Technology (2013) "Integrating Clinical Decision Support Tools into Ambulatory Care Workflows for Improved Outcomes and Patient Safety" at <https://www.healthit.gov/sites/default/files/clinical-decision-support-0913.pdf>.

⁹⁰ Hedegaard, H., Warner, M., & Miniño, A. M. (2017). NCHS Data Brief No. 294. Center for Disease Control and Prevention National Center for Health Statistics. Available at <https://www.cdc.gov/nchs/products/databriefs/db294.htm>.

⁹¹ Park-Lee, E., Lipari, R. N., Hedden, S. L., Kroutil, L. A., & Porter, J. D. (2017). Receipt of Services for Substance Use and Mental Health Issues among Adults: Results from the 2016 National Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration NSDUH Data Review. Available at <https://www.samhsa.gov/data/sites/default/files/NSDUH-DR-FFR2-2016/NSDUH-DR-FFR2-2016.htm>.

⁹² Centers for Medicare & Medicaid Services "Promoting Interoperability (PI)" resource may be found at <https://www.cms.gov/Regulations-andGuidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms/>.

TABLE B: Proposed Changes to Previously Adopted Improvement Activities for the MIPS CY 2019 Performance Period and Future Years

Current Improvement Activity	
Current Activity ID:	IA CC 10
Current Subcategory:	Care Coordination
Current Activity Title:	Care transition documentation practice improvements
Current Activity Description:	Implementation of practices/processes for care transition that include documentation of how a MIPS eligible clinician or group carried out a patient-centered action plan for first 30 days following a discharge (e.g., staff involved, phone calls conducted in support of transition, accompaniments, navigation actions, home visits, patient information access).
Current Weighting:	Medium
Proposed Changes and Rationale:	Addition of "...real time communication between PCP and consulting clinicians; PCP included on specialist follow-up or transition communications" as additional examples of how a patient-centered action plan could be documented. Primary care physicians are considered the gatekeeper of patient care. Including them in communications from specialists to patients about their follow-up of transition-of-care promotes continuity between clinicians. Adding this example to this improvement activity underscores the important role specialists play in care transition documentation practice improvement. Other language was revised for clarity.
Proposed Revised Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must document practices/processes for care transition with documentation of how a MIPS eligible clinician or group carried out an action plan for the patient with the patient's preferences in mind (that is, a "patient-centered" plan) during the first 30 days following a discharge. Examples of these practices/processes for care transition include: staff involved in the care transition; phone calls conducted in support of transition; accompaniments of patients to appointments or other navigation actions; home visits; patient information access to their medical records; real time communication between PCP and consulting clinicians; PCP included on specialist follow-up or transition communications.
Current Improvement Activity	
Current Activity ID:	IA PM 9
Current Subcategory:	Population Management
Current Activity Title:	Participation in Population Health Research
Current Activity Description:	Participation in research that identifies interventions, tools or processes that can improve a targeted patient population.
Current Weighting:	Medium
Proposed Changes and Rationale:	We are proposing to remove PM_9, because we believe PM_9 and PM_17 are duplicative and provide improvement activity credit for the same activity. In the CY 2017 Quality Payment Program final rule (81 FR 77820), we finalized PM_9: Participation in Population Health Research (activity title); Participation in research that identifies interventions, tools or processes that can improve a targeted patient population (activity description). In the CY 2018 Quality Payment Program final rule (82 FR 54481), we finalized PM_17: Participation in Population Health Research (activity title); participation in federally and/or privately funded research that identifies interventions tools, or processes that can improve a targeted patient population (activity description). We believe PM_9 and PM_17 are duplicative because they include the same subcategory and activity title, and nearly an identical description of the activity; participation in "research that identifies interventions, tools, or processes that can improve a targeted patient population." The two activities are only distinguished by the inclusion in the description for PM_17 specifying that clinicians can meet this activity through participation in federally and/or privately funded research that PM_9 does not. Therefore, we are proposing to remove PM_9 and preserve PM_17 so that we will have a consolidated activity that encompasses both improvement activities.
Proposed Revised Activity Description:	N/A
Current Improvement Activity	
Current Activity ID:	IA PM 13
Current Subcategory:	Population Management
Current Activity Title:	Chronic Care and Preventative Care Management for Empaneled Patients
Current Activity Description:	Proactively manage chronic and preventive care for empaneled patients that could include one

Description:	<p>or more of the following:</p> <ul style="list-style-type: none"> • Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; and plan of care for chronic conditions; • Use condition-specific pathways for care of chronic conditions (e.g., hypertension, diabetes, depression, asthma and heart failure) with evidence-based protocols to guide treatment to target; such as a CDC-recognized diabetes prevention program; • Use pre-visit planning to optimize preventive care and team management of patients with chronic conditions; • Use panel support tools (registry functionality) to identify services due; • Use predictive analytical models to predict risk, onset and progression of chronic diseases; or • Use reminders and outreach (e.g., phone calls, emails, postcards, patient portals and community health workers where available) to alert and educate patients about services due; and/or routine medication reconciliation.
Current Weighting:	Medium
Proposed Changes and Rationale:	<p>Addition of examples of evidence based, condition-specific pathways for care of chronic conditions: “These might include, but are not limited to, the NCQA Diabetes Recognition Program (DRP) and the NCQA Heart/Stroke Recognition Program (HSRP).”</p> <p>These examples relating to diabetes, heart, and stroke pathways are examples of evidence based, condition-specific pathways for care of chronic conditions. These additions to this activity provide specialist-specific examples of actions that can be taken to meet the intent of this activity. We have received stakeholder feedback that additional specialty-specific activities would be welcome in the improvement activities inventory. Other language was revised for clarity.</p>
Proposed Revised Activity Description:	<p>In order to receive credit for this activity, a MIPS eligible clinician must manage chronic and preventive care for empaneled patients (that is, patients assigned to care teams for the purpose of population health management), which could include one or more of the following actions:</p> <ul style="list-style-type: none"> • Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; and plan of care for chronic conditions; • Use evidence based, condition-specific pathways for care of chronic conditions (for example, hypertension, diabetes, depression, asthma, and heart failure). These might include, but are not limited to, the NCQA Diabetes Recognition Program (DRP)⁹³ and the NCQA Heart/Stroke Recognition Program (HSRP)⁹⁴. • Use pre-visit planning, that is, preparations for conversations or actions to propose with patient before an in-office visit to optimize preventive care and team management of patients with chronic conditions; • Use panel support tools, (that is, registry functionality) or other technology that can use clinical data to identify trends or data points in patient records to identify services due; • Use predictive analytical models to predict risk, onset and progression of chronic diseases; and/or • Use reminders and outreach (e.g., phone calls, emails, postcards, patient portals, and community health workers where available) to alert and educate patients about services due; and/or routine medication reconciliation.
Current Improvement Activity	
Current Activity ID:	IA_PSPA_2
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Participation in MOC Part IV

⁹³ Diabetes Recognition Program information may be found at

<http://www.ncqa.org/programs/recognition/clinicians/diabetes-recognition-program-drp>.

⁹⁴ NCQA Heart/Stroke Recognition Program information may be found at

<http://www.ncqa.org/programs/recognition/clinicians/heart-stroke-recognition-program-hsrp>.

Current Activity Description:	Participation in Maintenance of Certification (MOC) Part IV, such as the American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program, National Cardiovascular Data Registry (NCDR) Clinical Quality Coach, Quality Practice Initiative Certification Program, American Board of Medical Specialties Practice Performance Improvement Module or American Society of Anesthesiologists (ASA) Simulation Education Network, for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of monthly activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.
Current Weighting:	Medium
Proposed Changes and Rationale:	<p>Added two examples of ways in which a MIPS eligible clinician can participate in Maintenance of Certification (MOC) Part IV: participation in “specialty-specific activities including Safety Certification in Outpatient Practice Excellence (SCOPE)⁹⁵,” and “American Psychiatric Association (APA) Performance in Practice modules⁹⁶.”</p> <p>These additions to the activity provide specialist-specific examples of actions that can be taken to meet this activity. We have received stakeholder feedback through listening sessions and meetings with various stakeholder entities that additional specialty-specific activities would be welcome in the Inventory. Specifically, adding these examples of activities in psychiatry and obstetrics and gynecology, respectively, fill a gap in the Inventory. Other language was revised for clarity.</p>
Proposed Revised Activity Description:	<p>In order to receive credit for this activity, a MIPS eligible clinician must participate in Maintenance of Certification (MOC) Part IV⁹⁷. Maintenance of Certification (MOC) Part IV requires clinicians to perform monthly activities across practice to regularly assess performance by reviewing outcomes addressing identified areas for improvement and evaluating the results.</p> <p>Some examples of activities that can be completed to receive MOC Part IV credit are: the American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program,⁹⁸ National Cardiovascular Data Registry (NCDR) Clinical Quality Coach,⁹⁹ Quality Practice Initiative Certification Program,¹⁰⁰ American Board of Medical Specialties Practice Performance Improvement Module¹⁰¹ or American Society of Anesthesiologists (ASA) Simulation Education Network,¹⁰² for improving professional practice including participation</p>

⁹⁵Safety Certification in Outpatient Practice Excellence for Women's Health resource may be found at <https://psnet.ahrq.gov/resources/resource/24964/acog-scope-safety-certification-in-outpatient-practice-excellence-for-womens-health>.

⁹⁶Certification and Licensure in Psychiatry, for ABMS Maintenance of Certification Part IV resource may be found at <https://www.psychiatry.org/psychiatrists/education/certification-and-licensure/moc-part-4>.

⁹⁷American Board of Medical Specialties Maintenance of Certification Part IV resource may be found at <http://www.abms.org/board-certification/steps-toward-initial-certification-and-moc/>.

⁹⁸American Board of Internal Medicine Approved Quality Improvement Program resource may be found at <http://www.abim.org/reference-pages/approved-activities.aspx>

⁹⁹American College of Cardiology National Cardiovascular Data Registry Clinical Quality Coach Practice Dashboard resource may be found at <https://cvquality.acc.org/NCDR-Home/clinical-quality-coach/marketing>

¹⁰⁰American Society of Clinical Oncology Quality Oncology Practice Initiative Certification Program resource may be found at <https://practice.asco.org/quality-improvement/quality-programs/qopi-certification-program>

¹⁰¹American Board of Medical Specialties Multi-Specialty Portfolio Program resource may be found at <https://mocportfolioprogram.org/about-us/>

¹⁰²American Society of Anesthesiologists Simulation Education Network resource may be found at [https://education.asahq.org/totara/asa/core/drupal.php?name=MOCA%202.0%20Endorsed%20Simulation%20Centers%20-%20American%20Society%20of%20Anesthesiologists%20\(ASA\)&_ga=2.105495681.383908935.1527123081-1839415368.1527123081](https://education.asahq.org/totara/asa/core/drupal.php?name=MOCA%202.0%20Endorsed%20Simulation%20Centers%20-%20American%20Society%20of%20Anesthesiologists%20(ASA)&_ga=2.105495681.383908935.1527123081-1839415368.1527123081)

	in a local, regional or national outcomes registry or quality assessment program; specialty-specific activities including Safety Certification in Outpatient Practice Excellence (SCOPE); ¹⁰³ American Psychiatric Association (APA) Performance in Practice modules. ¹⁰⁴
Current Improvement Activity	
Current Activity ID:	IA PSPA 8
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of Patient Safety Tools
Current Activity Description:	Use of tools that assist specialty practices in tracking specific measures that are meaningful to their practice, such as use of a surgical risk calculator, evidence based protocols such as Enhanced Recovery After Surgery (ERAS) protocols, the CDC Guide for Infection Prevention for Outpatient Settings, (https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html), predictive algorithms, or similar tools.
Current Weighting:	Medium
Proposed Changes and Rationale:	Addition of “opiate risk tool (ORT), or other similar tools” as an additional example/category of an action that can be undertaken to meet the requirements of this activity. This addition highlights an evidence-based tool that can be deployed to assess opiate risk and addresses the CMS Meaningful Measures area of Prevention and Treatment of Opioid and Substance Use Disorders. ¹⁰⁵ Other language was revised for clarity.
Proposed Revised Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must use tools that assist specialty practices in tracking specific measures that are meaningful to their practice. Some examples of tools that could satisfy this activity are: a surgical risk calculator; evidence based protocols, such as Enhanced Recovery After Surgery (ERAS) protocols; ¹⁰⁶ the Centers for Disease Control (CDC) Guide for Infection Prevention for Outpatient Settings ¹⁰⁷ predictive algorithms; and the opiate risk tool (ORT) ¹⁰⁸ or similar tool.
Current Improvement Activity	
Current Activity ID:	IA PSPA 17
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Implementation of analytic capabilities to manage total cost of care for practice population
Current Activity Description:	Build the analytic capability required to manage total cost of care for the practice population that could include one or more of the following: Train appropriate staff on interpretation of cost and utilization information; and/or Use available data regularly to analyze opportunities to reduce cost through improved care.
Current Weighting:	Medium
Proposed Changes and Rationale:	Added an example platform that uses available data to analyze opportunities to reduce cost through improved care: “An example of a platform with the necessary analytic capability is the American Society for Gastrointestinal (GI) Endoscopy’s GI Operations Benchmarking Platform.” ¹⁰⁹

¹⁰³ American College of Obstetricians and Gynecologists Safety Certification in Outpatient Practice Excellence for Women’s Health resource may be found at <https://www.acog.org/About-ACOG/ACOG-Departments/VRQC-and-SCOPE/SCOPE-Program-Overview>

¹⁰⁴ American Psychiatric Association Learning Center resource may be found at <https://education.psychiatry.org/Users/ProductList.aspx?TypeID=8>

¹⁰⁵ Centers for Medicare & Medicaid Services “Meaningful Measures Hub” resource can be found at [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html#Measure Areas Defined](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html#Measure%20Areas%20Defined)

¹⁰⁶ Enhanced Recovery After Surgery (ERAS) protocols can be found at <http://aserhq.org/protocols/>.

¹⁰⁷ The Centers for Disease Control (CDC) Guide for Infection Prevention for Outpatient Settings can be found at <https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html>.

¹⁰⁸ The Opiate Risk Tool can be found at <https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf>.

¹⁰⁹ American Society for Gastrointestinal Endoscopy GI Operations Benchmarking can be found at <https://www.asge.org/home/practice-support/gi-operations-benchmarking>.

	Based on stakeholder feedback, we are proposing to add this example to clarify what type of a platform has the analytic capability to improve and manage total cost of care for the practice population described. Other language was revised for clarity.
Proposed Revised Activity Description:	<p>In order to receive credit for this activity, a MIPS eligible clinician must conduct or build the capacity to conduct analytic activities to manage total cost of care for the practice population. Examples of these activities could include:</p> <ol style="list-style-type: none">1.) Train appropriate staff on interpretation of cost and utilization information;2.) Use available data regularly to analyze opportunities to reduce cost through improved care. An example of a platform with the necessary analytic capability to do this is the American Society for Gastrointestinal (GI) Endoscopy's GI Operations Benchmarking Platform.

We solicit comment on our proposals to modify or remove the improvement activities as discussed in Table B for the MIPS CY 2019 performance period and future years.



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Part III

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 219

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Northwest Fisheries Science Center Fisheries Research; Final Rule

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 219**

[Docket No. 151027994–6421–02]

RIN 0648–BF47

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Northwest Fisheries Science Center Fisheries Research

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

ACTION: Final rule.

SUMMARY: NMFS' Office of Protected Resources (OPR), upon request of NMFS' Northwest Fisheries Science Center (NWFSC), hereby issues regulations to govern the unintentional taking of marine mammals incidental to fisheries research conducted in the Pacific Ocean over the course of five years. These regulations, which allow for the issuance of Letters of Authorization (LOA) for the incidental take of marine mammals during the described activities and specified timeframes, prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, as well as requirements pertaining to the monitoring and reporting of such taking.

DATES: Effective from August 27, 2018, through August 28, 2023.

ADDRESSES: A copy of NWFSC's application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: www.fisheries.noaa.gov/action/incidental-take-authorization-noaa-fisheries-nwfs-fisheries-and-ecosystem-research. In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:**Purpose and Need for Regulatory Action**

These regulations, issued under the authority of the Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361 *et seq.*), establish a framework for authorizing the take of marine mammals incidental to the NWFSC's fisheries research activities in the California Current and Pacific Northwest.

The NWFSC collects a wide array of information necessary to evaluate the status of exploited fishery resources and the marine environment. NWFSC scientists conduct fishery-independent research onboard NOAA-owned and operated vessels or on chartered vessels. A few surveys are conducted onboard commercial fishing vessels, but the NWFSC designs and executes the studies and funds vessel time.

We received an application from the NWFSC requesting five-year regulations and authorization to take multiple species of marine mammals. Take is anticipated to occur by Level B harassment incidental to the use of active acoustic devices, as well as by visual disturbance of pinnipeds, and by Level A harassment, serious injury, or mortality incidental to the use of fisheries research gear. The regulations are valid for five years from the date of issuance. Please see "Background" below for definitions of harassment.

Legal Authority for the Proposed Action

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region for up to five years if, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity, as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I provide the legal basis for issuing this final rule containing five-year regulations, and a subsequent LOA. As directed by this legal authority, this final rule contains mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Final Rule

The following provides a summary of some of the major provisions within the rulemaking for the NWFSC fisheries research activities. We have determined that the NWFSC's adherence to the planned mitigation, monitoring, and reporting measures listed below will achieve the least practicable adverse impact on the affected marine mammals. They include:

- Required monitoring of the sampling areas to detect the presence of marine mammals before deployment of certain research gear.
- Required use of acoustic deterrent devices on surface trawl nets.

- Required implementation of the mitigation strategy known as the "move-on rule mitigation protocol" which incorporates best professional judgment, when necessary during certain research fishing operations.

Background

Paragraphs 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1371(a)(5)(A) and (D)) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined "negligible impact" in 50 CFR 216.103 as "an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On August 10, 2015, we received an adequate and complete request from NWFSC for authorization to take marine mammals incidental to fisheries research activities. We received an initial draft of the request on January 2, 2015, followed by a revised draft on April 28, 2015. On August 28, 2015 (80 FR 52256), we published a notice of receipt of NWFSC's application in the **Federal Register**, requesting comments and information related to the NWFSC

request for 30 days. We received comments jointly from The Humane Society of the United States and Whale and Dolphin Conservation, which we considered in development of the notice of proposed rulemaking (81 FR 38516; June 13, 2016) and which are available online at: www.fisheries.noaa.gov/action/incidental-take-authorization-noaa-fisheries-nwfs-fisheries-and-ecosystem-research.

NWFSC plans to conduct fisheries research with trawl gear used at various levels in the water column, hook-and-line gears (including longlines with multiple hooks, rod and reel, and troll deployments), purse seine/tangle net gear, and other gear. If a marine mammal interacts with gear deployed by NWFSC, the outcome could potentially be Level A harassment, serious injury (*i.e.*, any injury that will likely result in mortality), or mortality. Therefore, NWFSC has pooled the estimated number of incidents of take that could reasonably result from gear interactions, and we have assessed the potential impacts accordingly. NWFSC also uses various active acoustic devices in the conduct of fisheries research, and use of these devices has the potential to result in Level B harassment of marine mammals. Level B harassment of pinnipeds hauled out may also occur, as a result of visual disturbance from vessels conducting NWFSC research. These regulations are valid for five years from the date of issuance.

NWFSC requests authorization to take individuals of 16 species by Level A harassment, serious injury, or mortality (hereafter referred to as M/SI) and of 34 species by Level B harassment.

Description of the Specified Activity

Overview

The NWFSC collects a wide array of information necessary to evaluate the status of exploited fishery resources and the marine environment. NWFSC scientists conduct fishery-independent research onboard NOAA-owned and operated vessels or on chartered vessels. A few surveys are conducted onboard commercial fishing vessels, but the NWFSC designs and executes the studies and funds vessel time. The NWFSC plans to administer and conduct approximately 36 survey programs over the 5-year period. The gear types used fall into several categories: Towed nets fished at various levels in the water column, longline and other hook and line gear, seine nets, traps, and other gear. Only use of trawl nets, hook and line gears, and purse seine nets are likely to result in interaction with marine mammals.

Many of these surveys also use active acoustic devices.

The Federal government has a responsibility to conserve and protect living marine resources in U.S. waters and has also entered into a number of international agreements and treaties related to the management of living marine resources in international waters outside the United States. NOAA has the primary responsibility for managing marine finfish and shellfish species and their habitats, with that responsibility delegated within NOAA to NMFS.

In order to direct and coordinate the collection of scientific information needed to make informed fishery management decisions, Congress created six regional fisheries science centers, each a distinct organizational entity and the scientific focal point within NMFS for region-based, Federal fisheries-related research. This research is aimed at monitoring fish stock recruitment, abundance, survival and biological rates, geographic distribution of species and stocks, ecosystem process changes, and marine ecological research. The NWFSC is the research arm of NMFS in the northwest region of the United States. The NWFSC conducts research and provides scientific advice to manage fisheries and conserve protected species in the geographic research area described below and provides scientific information to support the Pacific Fishery Management Council and numerous other domestic and international fisheries management organizations.

Dates and Duration

The specified activity may occur at any time during the five-year period of validity of the regulations. Dates and duration of individual surveys are inherently uncertain, based on congressional funding levels for the NWFSC, weather conditions, or ship contingencies. In addition, cooperative research is designed to provide flexibility on a yearly basis in order to address issues as they arise. Some cooperative research projects last multiple years or may continue with modifications. Other projects only last one year and are not continued. Most cooperative research projects go through an annual competitive selection process to determine which projects should be funded based on proposals developed by many independent researchers and fishing industry participants.

Specified Geographical Region

The NWFSC conducts research in the Pacific Northwest and California Current within three research areas: The California Current Research Area

(CCRA), Puget Sound Research Area (PSRA), and Lower Columbia River Research Area (LCRRA). Please see Figures 1–2 through 1–4 in the NWFSC application for maps of the three research areas. We note here that, while the NWFSC specified geographical region extends outside of the U.S. Exclusive Economic Zone (EEZ), from the Mexican EEZ (not including Mexican territorial waters) north into the Canadian EEZ (not including Canadian territorial waters), the MMPA's authority does not extend into foreign territorial waters. These areas were described in detail in our notice of proposed rulemaking (81 FR 38516; June 13, 2016); please see that document for further detail.

Detailed Description of Activities

A detailed description of NWFSC's planned activities was provided in our notice of proposed rulemaking (81 FR 38516; June 13, 2016) and is not repeated here. No changes have been made to the specified activities described therein.

Comments and Responses

We published a notice of proposed rulemaking in the **Federal Register** on June 13, 2016 (81 FR 38516; June 13, 2016), and requested comments and information from the public. During the thirty-day comment period, we received a letter from the Marine Mammal Commission (Commission). The comments and our responses are provided here, and the comments have been posted online at:

www.fisheries.noaa.gov/action/incidental-take-authorization-noaa-fisheries-nwfs-fisheries-and-ecosystem-research. Please see the comment letter for full rationale behind the recommendations we respond to below. No changes were made to the proposed rule as a result of these comments.

Comment 1: The Commission provides general recommendations—not specific to the proposed NWFSC rulemaking—that NMFS develop criteria and guidance for determining when prospective applicants should request taking by Level B harassment from the use of echosounders, other sonars, and sub-bottom profilers and that NMFS formulate a strategy for updating its generic behavioral harassment thresholds for all types of sound sources as soon as possible.

Response: We appreciate the recommendations and will consider the need for applicant guidance specific to the types of acoustic sources mentioned by the Commission. Generally speaking, there has been a lack of information and scientific consensus regarding the

potential effects of scientific sonars on marine mammals, which may differ depending on the system and species in question as well as the environment in which the system is operated. We are currently working to ensure that the use of these types of active acoustic sources is considered consistently and look forward to the Commission's advice as we proceed.

With regard to revision of existing behavioral harassment criteria, NMFS agrees that this is necessary. NMFS is continuing our examination of the effects of noise on marine mammal behavior and plans to focus our work in the coming years on developing guidance regarding the effects of anthropogenic sound on marine mammal behavior. Behavioral response is a complex question and we have determined that additional time is needed to research and address it appropriately.

Comment 2: The Commission recommends that OPR require NWFSC to estimate the numbers of marine mammals taken by Level B harassment incidental to use of active acoustic sources (e.g., echosounders) based on the 120-decibel (dB) rather than the 160-dB root mean square (rms) threshold.

Response: Please see our notice of proposed rulemaking (81 FR 38516; June 13, 2016) for discussion related to acoustic terminology and thresholds. The Commission repeats a recommendation made in prior letters and, as we have previously indicated, we disagree with the recommendation. Our previous response is repeated below.

Continuous sounds are those whose sound pressure level remains above that of the ambient sound, with negligibly small fluctuations in level (NIOSH, 1998; ANSI, 2005), while intermittent sounds are defined as sounds with interrupted levels of low or no sound (NIOSH, 1998). Thus, echosounder signals are not continuous sounds but rather intermittent sounds. Intermittent sounds can further be defined as either impulsive or non-impulsive. Impulsive sounds have been defined as sounds which are typically transient, brief (<1 sec), broadband, and consist of a high peak pressure with rapid rise time and rapid decay (ANSI, 1986; NIOSH, 1998). Echosounder signals also have durations that are typically very brief (<1 sec), with temporal characteristics that more closely resemble those of impulsive sounds than non-impulsive sounds, which typically have more gradual rise times and longer decays (ANSI, 1995; NIOSH, 1998). With regard to behavioral thresholds, we consider the temporal and spectral characteristics of

echosounder signals to more closely resemble those of an impulse sound than a continuous sound.

The Commission suggests that, for certain sources considered here, the interval between pulses would not be discernible to the animal, rendering them effectively continuous. However, echosounder pulses are emitted in a similar fashion as odontocete echolocation click trains. Research indicates that marine mammals, in general, have extremely fine auditory temporal resolution and can detect each signal separately (e.g., Au *et al.*, 1988; Dolphin *et al.*, 1995; Supin and Popov, 1995; Mooney *et al.*, 2009), especially for species with echolocation capabilities. Therefore, it is highly unlikely that marine mammals would perceive echosounder signals as being continuous.

In conclusion, echosounder signals are intermittent rather than continuous signals, and the fine temporal resolution of the marine mammal auditory system allows them to perceive these sounds as such. Further, the physical characteristics of these signals indicate a greater similarity to the way that intermittent, impulsive sounds are received. Therefore, the 160-dB threshold (typically associated with impulsive sources) is more appropriate than the 120-dB threshold (typically associated with continuous sources) for estimating takes by behavioral harassment incidental to use of such sources. This response represents the consensus opinion of acoustics experts from NMFS' Office of Protected Resources and Office of Science and Technology.

Comment 3: The Commission notes that NMFS has delineated two categories of acoustic sources, largely based on frequency, with those sources operating at frequencies greater than the known hearing ranges of any marine mammal (i.e., >180 kilohertz (kHz)) lacking the potential to cause disruption of behavioral patterns. The Commission describes the recent scientific literature on acoustic sources with frequencies above 180 kHz (i.e., Deng *et al.*, 2014; Hastie *et al.*, 2014) and recommends that we estimate numbers of takes associated with those acoustic sources (or similar acoustic sources) with frequencies above 180 kHz that have been shown to elicit behavioral responses above the 120-dB threshold.

Response: We considered the information cited by the Commission in our proposed rulemaking. NMFS's response regarding the appropriateness of the 120-dB versus 160-dB rms thresholds was provided above in the response to Comment #2. In general, the

referenced work indicates that "sub-harmonics" could be "detectable" by certain species at distances up to several hundred meters (m). However, this detectability is in reference to ambient noise, not to NMFS's established 160-dB threshold for assessing the potential for incidental take for these sources. A behavioral response to a stimulus does not necessarily indicate that Level B harassment, as defined by the MMPA, has occurred. Source levels of the secondary peaks considered in these studies—those within the hearing range of some marine mammals—range from 135–166 dB, meaning that these sub-harmonics would either be below the threshold for behavioral harassment or would attenuate to such a level within a few meters. Beyond these important study details, these high-frequency (i.e., Category 1) sources and any energy they may produce below the primary frequency that could be audible to marine mammals would be dominated by a few primary sources (e.g., EK60) that are operated near-continuously—much like other Category 2 sources considered in our assessment of potential incidental take from NWFSC's use of active acoustic sources—and the potential range above threshold would be so small as to essentially discount them.

Mitigation

In order to issue an incidental take authorization under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for subsistence uses. We provided a full description of the planned mitigation measures, including background discussion related to certain elements of the mitigation plan, in our notice of proposed rulemaking (81 FR 38516; June 13, 2016). Please see that document for more detail.

NMFS has considered many potential mitigation measures, including those the NWFSC has determined to be feasible and has implemented in recent years as a standard part of sampling protocols. These measures include the move-on rule mitigation protocol (also referred to in the preamble as the move-on rule), protected species visual watches and use of acoustic pingers on trawl gear, as well as use of a marine mammal excluder device (MMED) in Nordic 264 trawl nets.

General Measures

Coordination and communication—We require that the NWFSC take all necessary measures to coordinate and communicate in advance of each specific survey with NOAA's Office of Marine and Aviation Operations (OMAO), or other relevant parties, to ensure that all mitigation measures and monitoring requirements described herein, as well as the specific manner of implementation and relevant event-contingent decision-making processes, are clearly understood and agreed-upon. This may involve description of all required measures when submitting cruise instructions to OMAO or when completing contracts with external entities. NWFSC will coordinate and conduct briefings at the outset of each survey and as necessary between the ship's crew (commanding officer/master or designee(s), as appropriate) and scientific party in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures. The chief scientist (CS) will be responsible for coordination with the Officer on Deck (OOD; or equivalent on non-NOAA platforms) to ensure that requirements, procedures, and decision-making processes are understood and properly implemented.

Vessel speed—Vessel speed during active sampling rarely exceeds 5 knots (kn), with typical speeds being 2–4 kn. Transit speeds vary from 6–14 kn but average 10 kn. These low vessel speeds minimize the potential for ship strike. At any time during a survey or in transit, if a crew member standing watch or dedicated marine mammal observer sights marine mammals that may intersect with the vessel course, that individual will immediately communicate the presence of marine mammals to the bridge for appropriate course alteration or speed reduction, as possible, to avoid incidental collisions.

Other gears—The NWFSC deploys a wide variety of gear to sample the marine environment during all of their research cruises. Many of these types of gear (e.g., plankton nets, video camera and remotely-operated vehicle (ROV) deployments) are not considered to pose any risk to marine mammals and are therefore not subject to specific mitigation measures. However, at all times when the NWFSC is conducting survey operations at sea, the OOD and/or CS and crew will monitor for any unusual circumstances that may arise at a sampling site and use best professional judgment to avoid any potential risks to marine mammals during use of all research equipment.

Handling procedures—The NWFSC will implement a number of handling protocols to minimize potential harm to marine mammals that are incidentally taken during the course of fisheries research activities. In general, protocols have already been prepared for use on commercial fishing vessels. Because incidental take of marine mammals in fishing gear is similar for commercial fisheries and research surveys, NWFSC proposes to adopt these protocols, which are expected to increase post-release survival. In general, following a “common sense” approach to handling captured or entangled marine mammals will present the best chance of minimizing injury to the animal and of decreasing risks to scientists and vessel crew. Handling or disentangling marine mammals carries inherent safety risks, and using best professional judgment and ensuring human safety is paramount.

Captured live or injured marine mammals are released from research gear and returned to the water as soon as possible with no gear or as little gear remaining on the animal as possible. Animals are released without removing them from the water if possible, and data collection is conducted in such a manner as not to delay release of the animal(s) or endanger the crew. NWFSC staff will be instructed on how to identify different species, handle and bring marine mammals aboard a vessel, assess the level of consciousness, remove fishing gear, and return marine mammals to water.

Trawl Survey Visual Monitoring and Operational Protocols

Specific mitigation protocols are required for all trawl operations conducted by the NWFSC using Nordic 264 surface trawl gear, midwater trawl gear (modified Cobb, Aleutian Wing, and various commercial nets), and bottom trawl gear (double-rigged shrimp, Poly Nor'easter, modified Aberdeen, beam, and various commercial nets). Separate protocols (described below) are in place for the Kodiak surface trawl and pair trawl gear. Marine mammal watches will be conducted for at least ten minutes prior to the beginning of the planned set and throughout the tow and net retrieval, by scanning the surrounding waters with the naked eye and rangefinding binoculars (or monocular). Lookouts immediately alert the OOD and CS as to their best estimate of the species and number of animals observed and any observed animal's distance, bearing, and direction of travel relative to the ship's position. The CS must confirm with the OOD that no marine mammals have

been seen within 500 m (or as far as may be observed if less than 500 m) of the ship or appear to be approaching the ship during the pre-set watch period prior to the deployment of any trawl gear. During nighttime operations, visual observation may be conducted using the naked eye and available vessel lighting but effectiveness is limited. The visual observation period typically occurs during transit leading up to arrival at the sampling station, rather than upon arrival on station. However, in some cases it may be necessary to conduct a plankton tow or other small net cast prior to deploying trawl gear. In these cases, the visual watch will continue until trawl gear is ready to be deployed. Aside from pre-trawl monitoring, the OOD/CS and crew standing watch will visually scan for marine mammals during all daytime operations.

It is important to note that the 500 m distance is provided only as a frame of reference for marine mammal observations that would nominally be of greater concern as regards the potential for interaction with research fishing gear. The primary concern is to avoid all marine mammal interactions (regardless of the numbers of takes proposed for authorization here), and the most appropriate course of action to achieve this goal in any given instance is likely to be related more to event-specific elements than to an arbitrary distance from the vessel. Depending on unpredictable contextual elements, animals sighted at distances greater than 500 m could provoke mitigation action or, conversely, animals sighted at closer range could be determined to not be at risk of interacting with research fishing gear. The NWFSC considers 500 m to be the average effective observation distance, but the actual effective range is determined by numerous factors related to the weather, ship observations, and the species observed.

The primary purpose of conducting pre-trawl visual monitoring is to implement the move-on rule. If marine mammals are sighted within 500 m (or as far as may be observed if less than 500 m) of the vessel and are considered at risk of interacting with the vessel or research gear, or appear to be approaching the vessel and are considered at risk of interaction, NWFSC may elect to either remain onsite to see if the animals move off or may move on to another sampling location. When remaining onsite, the set is delayed (typically for at least ten minutes) and, if the animals depart or appear to no longer be at risk of interacting with the vessel or gear, a further ten minute observation period is

conducted. If no further observations are made or the animals still do not appear to be at risk of interaction, then the set may be made. If the vessel is moved to a different section of the sampling area, move-on rule mitigation protocols would begin anew. If, after moving on, marine mammals remain at risk of interaction, the CS or watch leader may decide to move again or to skip the station. Marine mammals that are sighted further than 500 m from the vessel would be monitored to determine their position and movement in relation to the vessel. If they appear to be closing on the vessel, the move-on rule protocols may be implemented even if they are initially further than 500 m from the vessel.

For surface trawl surveys (*i.e.*, those surveys deploying the Nordic 264 net), which have historically presented the greatest risk of marine mammal interaction, dedicated crew are assigned to marine mammal monitoring duty (*i.e.*, have no other tasks) and care is taken to provide some rest periods for observers to avoid fatigue. At least two pairs of binoculars are available for verification of potential sightings. As the vessel approaches the station, the OOD and at least one assigned member of the scientific party monitor for marine mammals. Within several minutes of arriving on station and finishing their sampling duties, two additional members of the scientific party are assigned to monitor for marine mammals and, for the remainder of the tow, there would be a minimum of three members of the scientific party watching for marine mammals. Depending on the situational context (*e.g.*, numbers of marine mammals seen during the station approach or expected at that particular place and season), additional crew may be assigned to stand watch as necessary to provide full monitoring coverage around the vessel. Up to eight observers in total (including ship's crew standing watch) may be on duty during active trawling. The focus on the full area around the ship continues until trawl retrieval begins, at which point observational focus turns to the stern and the trawl net itself.

For midwater and bottom trawl surveys, the pre-set watch period is conducted by the OOD and bridge crew and typically occurs during transit prior to arrival at the sampling station but may also include time on station if other types of gear or equipment (*e.g.*, bongo nets) are deployed before the trawl. For these trawls, risk of interaction during the tow is lower and monitoring effort is reduced to the bridge crew until trawl retrieval.

For all surveys, although the minimum pre-set watch period is ten minutes, the actual monitoring period is typically longer. During standard trawl operations, at least some of the trackline to be towed is typically traversed prior to setting gear in order to check for hazards. On surface trawl surveys, CTD casts and plankton/bongo net hauls are made prior to setting the trawl. These activities can take 25–35 minutes after the vessel arrives on station, depending on water depth, and monitoring for marine mammals continues throughout these activities. Midwater trawls and bottom trawls do not typically deploy other gears before deploying trawl gear, but reconnaissance of the trackline often takes ten to fifteen minutes after arriving on station. In addition, once the decision is made to deploy the trawl gear, monitoring continues while the net is unspooled, which may take about ten minutes. Before the trawl doors are deployed, the net floats closed on the surface behind the vessel, and appropriate actions can be taken if marine mammals are sighted near the ship. Therefore, the marine mammal monitoring period—which begins before the vessel arrives on station and extends continuously through gear deployment—typically extends for over thirty minutes for all trawl types.

The effectiveness of visual monitoring may be limited depending on weather and lighting conditions. The OOD, CS, or watch leader will determine the best strategy to avoid potential takes of marine mammals based on the species encountered and their numbers and behavior, position, and vector relative to the vessel, as well as any other factors. For example, a whale transiting through the sampling area in the distance may only require a short move from the designated station, whereas a pod of dolphins in close proximity to the vessel may require a longer move from the station or possibly cancellation of the planned tow if the group follows the vessel.

In general, trawl operations will be conducted immediately upon arrival on station (and on conclusion of the pre-watch period) in order to minimize the time during which marine mammals (particularly pinnipeds) may become attracted to the vessel. However, in some cases it will be necessary to conduct small net tows (*e.g.*, bongo net) prior to deploying trawl gear.

Once the trawl net is in the water, the OOD, CS, and/or crew standing watch will continue to visually monitor the surrounding waters and will maintain a lookout for marine mammal presence as far away as environmental conditions allow. If marine mammals are sighted

before the gear is fully retrieved, the most appropriate response to avoid marine mammal interaction will be determined by the professional judgment of the CS, watch leader, OOD and other experienced crew as necessary. This judgment will be based on past experience operating trawl gears around marine mammals (*i.e.*, best professional judgment) and on NWFSC training sessions that will facilitate dissemination of expertise operating in these situations (*e.g.*, factors that contribute to marine mammal gear interactions and those that aid in successfully avoiding such events). Best professional judgment takes into consideration the species, numbers, and behavior of the animals, the status of the trawl net operation (*e.g.*, net opening, depth, and distance from the stern), the time it would take to retrieve the net, and safety considerations for changing speed or course. We recognize that it is not possible to dictate in advance the exact course of action that the OOD or CS should take in any given event involving the presence of marine mammals in proximity to an ongoing trawl tow, given the sheer number of potential variables, combinations of variables that may determine the appropriate course of action, and the need to consider human safety in the operation of fishing gear at sea. Nevertheless, we require a full accounting of factors that shape both successful and unsuccessful decisions, and these details will be fed back into NWFSC training efforts and ultimately help to refine the best professional judgment that determines the course of action taken in any given scenario (see further discussion in “Monitoring and Reporting”).

If trawling operations have been suspended because of the presence of marine mammals, the vessel will resume trawl operations (when practicable) only when the animals are believed to have departed the area. This decision is at the discretion of the OOD/CS and is dependent on the situation.

Standard survey protocols that are expected to lessen the likelihood of marine mammal interactions include standardized tow durations and distances. Standard tow durations of not more than thirty minutes at the target depth will typically be implemented, excluding deployment and retrieval time (which may require an additional thirty minutes, depending on target depth), to reduce the likelihood of attracting and incidentally taking marine mammals. Short tow durations decrease the opportunity for marine mammals to find the vessel and investigate. Trawl tow distances will be

less than 3 nautical miles (nmi)—typically 1–2 nmi, depending on the specific survey and trawl speed—which is expected to reduce the likelihood of attracting and incidentally taking marine mammals. In addition, care will be taken when emptying the trawl to avoid damage to marine mammals that may be caught in the gear but are not visible upon retrieval. The gear will be emptied as quickly as possible after retrieval in order to determine whether or not marine mammals are present. The vessel's crew will clean trawl nets prior to deployment to remove prey items that might attract marine mammals. Catch volumes are typically small with every attempt made to collect all organisms caught in the trawl.

Marine mammal excluder device—Excluder devices are specialized modifications, typically used in trawl nets, which are designed to reduce bycatch by allowing non-target taxa to escape the net. These devices generally consist of a grid of bars fitted into the net that allow target species to pass through the bars into the codend while larger, unwanted taxa (e.g., turtles, sharks, mammals) strike the bars and are ejected through an opening in the net. Marine mammal excluder devices (MMED) have not been proven to be fully effective at preventing marine mammal capture in trawl nets (e.g., Chilvers, 2008) and are not expected to prevent marine mammal capture in NWFSC trawl surveys. It is difficult to effectively test such devices, in terms of effectiveness in excluding marine mammals as opposed to effects on target species catchability, because realistic field trials would necessarily involve marine mammal interactions with trawl nets. Use of artificial surrogates in field trials has not been shown to be a realistic substitute (Gibson and Isakssen, 1998). Nevertheless, we believe it reasonable to assume that use of MMEDs may reduce the likelihood of a given marine mammal interaction with trawl gear resulting in mortality. We do not infer causality, but note that annual marine mammal interactions with the Nordic 264 trawl net have been much reduced for NMFS's Southwest Fisheries Science Center (SWFSC) (relative to 2008) since their use of the MMED began.

Multiple types of midwater trawl nets are used in NWFSC trawl surveys. The Nordic 264 trawl net, used as a surface trawl by NWFSC, is generally much larger than the midwater trawls, is fished at faster speeds, and has a different shape and functionality than these nets. Very few marine mammal interactions with NWFSC pelagic trawl gear have involved nets other than the

Nordic 264 (one of 37 total incidents since 1999). Therefore, MMED use is not proposed for nets other than the Nordic 264.

The NWFSC has tested the MMED design used by the SWFSC and found that it caused a significant loss of some salmon species that were the target of their research. More recent experiments have used video cameras attached to the net opening and near the excluder device to test different configurations of the excluder device to minimize loss of target species. The experiments have looked at adding weight and stiffeners to the flap covering the escape hatch to keep it closed and flipping the MMED so the escape hatch faces down rather than up. Based on preliminary results, this downward-pointing escape hatch appears to be the best design for minimizing loss of target species. Additional research will be necessary to calibrate catch levels in tows with the excluder device compared to past tows that did not contain the excluder (i.e., to align the new catchability rates with historical data sets). During these configuration and calibration experiments some nets will be fished without the MMED in order to provide controls for catchability. Once the NWFSC completes these experiments the MMED will be used in all future trawls with the Nordic 264. Please see "Monitoring and Reporting" for additional discussion.

Acoustic deterrent devices—Acoustic deterrent devices (pingers) are underwater sound-emitting devices that have been shown to decrease the probability of interactions with certain species of marine mammals when fishing gear is fitted with the devices. Multiple studies have reported significant decreases in marine mammal interactions with fishing gear following pinger deployment, with results reported for multiple species and gears (e.g., Kraus *et al.*, 1997; Trippel *et al.*, 1999; Gearin *et al.*, 2000; Palka *et al.*, 2008; Barlow and Cameron, 2003, Carretta *et al.*, 2008; Carretta and Barlow, 2011). Pingers will be deployed during all surface trawl operations (i.e., using the Nordic 264 net), with two pairs of pingers installed near the net opening. The vessel's crew will ensure that pingers are operational prior to deployment. Pinger brands typically used by NWFSC include the Aquatec Subsea Limited model AQUAmark and Fumunda Marine models F10 and F70, with the following attributes: (1) Operational depth of 10–200 m; (2) tones range from 200–400 ms in duration, repeated every five to six seconds; (3) variable frequency of 10–

160 kHz; and (4) maximum source level of 145 dB rms re 1 μ Pa.

Kodiak surface trawl and pair trawl gear—The Kodiak surface trawl, used only in Puget Sound, has only limited potential for marine mammal interaction. This gear type is a small net towed at slow speeds (about 2 kn) as close to shore as the net can be fished, and these characteristics mean that marine mammals would likely be able to avoid the net or swim out of it if necessary. However, rules for cetaceans would be similar as for other net types (i.e., delay and/or move-on if cetaceans observed within approximately 500 m or clearly approaching from greater distance). If killer whales are observed at any distance, the net would not be deployed, and the move-on rule would be invoked.

The pair trawl is used only in the Columbia River and is fished with an open codend. Although unlikely, there is some potential for pinnipeds to become entangled in the net material. NWFSC's practice, which would be allowed under section 109(h) of the MMPA, is to deter pinnipeds from encountering the net using pyrotechnic devices and other measures. Therefore, separate mitigation is not warranted, and we do not discuss NWFSC deterrence of pinnipeds associated with pair trawl surveys further in this document. Please see the NWFSC's Programmatic Environmental Assessment (EA) for further information about this practice.

Longline and Other Hook and Line Survey Visual Monitoring and Operational Protocols

Visual monitoring requirements for all longline surveys are similar to the general protocols described above for trawl surveys. Please see that section for full details of the visual monitoring protocol and the move-on rule mitigation protocol. In summary, requirements for longline surveys are to: (1) Conduct visual monitoring during the 30-minute period prior to arrival on station; (2) implement the move-on rule if marine mammals are observed within the area around the vessel and may be at risk of interacting with the vessel or gear; (3) deploy gear as soon as possible upon arrival on station (depending on presence of marine mammals); and (4) maintain visual monitoring effort throughout deployment and retrieval of the longline gear. As was described for trawl gear, the OOD, CS, or watch leader will use best professional judgment to minimize the risk to marine mammals from potential gear interactions during deployment and retrieval of gear. If marine mammals are detected during

setting operations and are considered to be at risk, immediate retrieval or suspension of operations may be warranted. If operations have been suspended because of the presence of marine mammals, the vessel will resume setting (when practicable) only when the animals are believed to have departed the area. If marine mammals are detected during retrieval operations and are considered to be at risk, haul-back may be postponed. These decisions are at the discretion of the OOD/CS and are dependent on the situation. If killer whales are observed at any distance, the set would not occur and the move-on rule would be invoked.

Other types of hook and line surveys (e.g., rod and reel) generally use the same protocols as longline surveys. However, for hook and line surveys in Puget Sound the move-on rule is not required for pinnipeds because they are commonly abundant on shore nearby hook and line sampling locations. Use of the move-on rule in these circumstances would represent an impracticable impact on NWFSC survey operations, and we note that no marine mammals have ever been captured in NWFSC hook and line surveys. However, the NWFSC would implement the move-on rule for hook and line surveys in Puget Sound for any cetaceans that are within 500 m and may be at risk of interaction with the survey operation. If killer whales are observed at any distance, fishing would not occur.

As for trawl surveys, some standard survey protocols are expected to minimize the potential for marine mammal interactions. Soak times are typically short relative to commercial fishing operations, measured from the time the last hook is in the water to when the first hook is brought out of the water. NWFSC longline protocols specifically prohibit chumming (releasing additional bait to attract target species to the gear) and spent bait and offal is retained on the vessel until all gear has been retrieved. Some hook and line surveys use barbless hooks, which are less likely to injure a hooked animal.

Seine Survey Visual Monitoring and Operational Protocols

Visual monitoring and operational protocols for seine surveys are similar to those described previously for trawl surveys, with a focus on visual observation in the survey area and avoidance of marine mammals that may be at risk of interaction with survey vessels or gear. For purse seine operations, visual monitoring is focused on avoidance of cetaceans and aggregations of pinnipeds. Individual or

small numbers of pinnipeds may be attracted to purse seine operations, especially in Puget Sound, and are frequently observed to enter operational purse seines to depredate the catch and exit the net unharmed. Use of the move-on rule in these circumstances would represent an impracticable impact on NWFSC survey operations, and we note that no marine mammals have ever been captured in NWFSC seine surveys.

If pinnipeds are in the immediate vicinity of a purse seine survey, the set may be delayed until animals move away or the move-on rule is determined to be appropriate, but the net would not be opened if already deployed and pinnipeds enter it. However, delay would not be invoked if only few pinnipeds are present (e.g., less than five), and they do not appear to obviously be at risk.

If any dolphins or porpoises are observed within approximately 500 m of the purse seine survey location, the set would be delayed. If any dolphins or porpoises are observed in the net, the net would be immediately opened to free the animals. If killer whales or other large whales are observed at any distance the net would not be set, and the move-on rule would be invoked.

Beach seines are typically set nearshore by small boat crews, who visually survey the area prior to the set. The set would not be made within 200 m of any hauled pinnipeds. Otherwise, marine mammals are unlikely to be at risk of interaction with NWFSC beach seine operations, as the nets are relatively small and deployed and retrieved slowly. If a marine mammal is observed attempting to interact with the beach seine gear, the gear would immediately be lifted and removed from the water.

Tangle net protocols—Tangle nets are used only in the Columbia River. NWFSC attempts to avoid pinnipeds by rotating sampling locations on a daily basis and by avoiding fishing near haulout areas. However, as was described for NWFSC use of pair trawl gear in the LCRRA, NWFSC also deters pinnipeds from interacting with tangle net gear as necessary using pyrotechnic devices and visual presence, a practice allowed under section 109(h) of the MMPA. Therefore, we do not discuss NWFSC deterrence of pinnipeds associated with tangle net surveys further in this document. Please see the NWFSC's draft Programmatic EA for further information about this practice. If pinniped presence in the vicinity of tangle net surveys is so abundant as to be uncontrollable through deterrence, sampling would be discontinued for a given day.

We have carefully evaluated the NWFSC's planned mitigation measures and considered a range of other measures in the context of ensuring that we prescribed the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another: (1) The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals, (2) the proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and (3) the practicability of the measure for applicant implementation.

Any mitigation measure(s) we prescribe should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

(1) Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal);

(2) A reduction in the number (total number or number at biologically important time or location) of individual marine mammals exposed to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing takes by behavioral harassment only);

(3) A reduction in the number (total number or number at a biologically important time or location) of times any individual marine mammal would be exposed to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing takes by behavioral harassment only);

(4) A reduction in the intensity of exposure to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing the severity of behavioral harassment only);

(5) Avoidance or minimization of adverse effects to marine mammal habitat, paying particular attention to the prey base, blockage or limitation of passage to or from biologically important areas, permanent destruction of habitat, or temporary disturbance of habitat during a biologically important time; and

(6) For monitoring directly related to mitigation, an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on our evaluation of the NWFSC's proposed measures, as well as

other measures we considered, we have determined that these mitigation measures provide the means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Description of Marine Mammals in the Area of the Specified Activity

We previously reviewed NWFSC's species descriptions—which summarize available information regarding status

and trends, distribution and habitat preferences, behavior and life history, and auditory capabilities of the potentially affected species—for accuracy and completeness and referred readers to Sections 3 and 4 of NWFSC's application, as well as to NMFS's Stock Assessment Reports (SARs; www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments). We also provided information related to all species with expected potential for occurrence in the specified geographical

region where NWFSC plans to conduct the specified activities, summarizing information related to the population or stock, including potential biological removal (PBR). Current information, as reported in the most recent final 2016 and draft 2017 SARs, is summarized in Table 1 below (Carretta *et al.*, 2017; Muto *et al.*, 2017; www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports).

Table 1. Marine Mammals Potentially Present in the Vicinity of NWFSC Research Activities.

Common name	Scientific name	Stock	Occurrence			ESA/MMPA status; Strategic (Y/N) ¹	Stock abundance (CV, N _{min} , most recent abundance survey) ²	PBR	Annual M/SI ³
			CC	LOR	PS				
Order Cetartiodactyla – Cetacea – Superfamily Mysticeti (baleen whales)									
Family Eschrichtiidae									
Gray whale	<i>Eschrichtius robustus</i>	Eastern North Pacific	X		X	-; N	20,990 (0.05; 20,125; 2011)	624	132
Family Balaenopteridae (rorquals)									
Humpback whale	<i>Megaptera novaeangliae kuzira</i>	California/Oregon/ Washington (CA/OR/WA)	X		X	E/D; Y	1,918 (0.03; 1,876; 2014)	11 ⁹	≥9.2
Minke whale	<i>Balaenoptera acutorostrata scammoni</i>	CA/OR/WA	X		X	-; N	636 (0.72; 369; 2014)	3.5	≥1.3
Sei whale	<i>B. borealis borealis</i>	Eastern North Pacific	X			E/D; Y	519 (0.4; 374; 2014)	0.75	0
Fin whale	<i>B. physalus physalus</i>	CA/OR/WA	X			E/D; Y	9,029 (0.12; 8,127; 2014)	81	≥2.0
Blue whale	<i>B. musculus musculus</i>	Eastern North Pacific	X			E/D; Y	1,647 (0.07; 1,551; 2011)	2.3 ⁹	≥0.2
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)									
Family Physeteridae									
Sperm whale	<i>Physeter macrocephalus</i>	CA/OR/WA	X			E/D; Y	1,997 (0.57; 1,270; 2014)	2.5	0.9
Family Kogiidae									
Pygmy sperm whale	<i>Kogia breviceps</i>	CA/OR/WA	X			-; N	4,111 (1.12; 1,924; 2014)	19.2	0
Dwarf sperm whale	<i>K. sima</i>	CA/OR/WA ⁵	X			-; N	Unknown	Undet.	0
Family Ziphiidae (beaked whales)									
Cuvier's beaked whale	<i>Ziphius cavirostris</i>	CA/OR/WA	X			-; Y	3,274 (0.67; 2,059; 2014)	21	<0.1
Baird's beaked whale	<i>Berardius bairdii</i>	CA/OR/WA	X			-; N	2,697 (0.6; 1,633; 2014)	16	0
Hubbs' beaked whale	<i>Mesoplodon carlhubbsi</i>	CA/OR/WA ⁶	X			-; Y	3,044 (0.54; 1,967; 2014)	20	0.1
Blainville's beaked	<i>M. densirostris</i>		X						

whale									
Ginkgo-toothed beaked whale	<i>M. ginkgodens</i>		X						
Perrin's beaked whale	<i>M. perrini</i>		X						
Lesser (pygmy) beaked whale	<i>M. peruvianus</i>		X						
Stejneger's beaked whale	<i>M. stejnegeri</i>		X						
Family Delphinidae									
Common bottlenose dolphin	<i>Tursiops truncatus truncatus</i>	CA/OR/WA Offshore	X			-; N	1,924 (0.54; 1,255; 2014)	11	≥1.6
		California Coastal	X			-; N	453 (0.06; 346; 2011)	2.7	≥2.0
Striped dolphin	<i>Stenella coeruleoalba</i>	CA/OR/WA	X			-; N	29,211 (0.2; 24,782; 2014)	238	≥0.8
Long-beaked common dolphin	<i>Delphinus delphis bairdii</i>	California	X			-; N	101,305 (0.49; 68,432; 2014)	657	≥35.4
Short-beaked common dolphin	<i>D. d. delphis</i>	CA/OR/WA	X			-; N	969,861 (0.17; 839,325; 2014)	8,393	≥40
Pacific white-sided dolphin	<i>Lagenorhynchus obliquidens</i>	CA/OR/WA	X		X	-; N	26,814 (0.28; 21,195; 2014)	191	7.5
Northern right whale dolphin	<i>Lissodelphis borealis</i>	CA/OR/WA	X			-; N	26,556 (0.44; 18,608; 2014)	179	3.8
Risso's dolphin	<i>Grampus griseus</i>	CA/OR/WA	X			-; N	6,336 (0.32; 4,817; 2014)	46	≥3.7
Killer whale	<i>Orcinus orca</i> ⁴	West Coast Transient ⁷	X	X	X	-; N	243 (n/a; 2009)	2.4	0
		Eastern North Pacific Offshore	X			-; N	240 (0.49; 162; 2014)	1.6	0
		Eastern North Pacific Southern Resident	X		X	E/D; Y	83 (n/a; 2016)	0.14	0
		Eastern North Pacific Northern Resident	X		X	-; N	261 (n/a; 2011)	1.96	0
Short-finned pilot whale	<i>Globicephala macrorhynchus</i>	CA/OR/WA	X			-; N	836 (0.79; 466; 2014)	4.5	1.2
Family Phocoenidae (porpoises)									
Harbor porpoise	<i>Phocoena phocoena vomerina</i>	Morro Bay	X			-; N	2,917 (0.41; 2,102; 2012)	21	≥0.6

		Monterey Bay	X			-; N	3,715 (0.51; 2,480; 2011)	25	0
		San Francisco-Russian River	X			-; N	9,886 (0.51; 6,625; 2011)	66	0
		Northern CA/Southern OR	X			-; N	35,769 (0.52; 23,749; 2011)	475	≥0.6
		Northern OR/WA Coast	X	X		-; N	21,487 (0.44; 15,123; 2011)	151	≥3
		Washington Inland Waters			X	-; N	11,233 (0.37; 8,308; 2015)	66	≥7.2
Dall's porpoise	<i>Phocoenoides dalli dalli</i>	CA/OR/WA	X	X	X	-; N	25,750 (0.45; 17,954; 2014)	172	0.3
Order Carnivora – Superfamily Pinnipedia									
Family Otariidae (eared seals and sea lions)									
Guadalupe fur seal	<i>Arctocephalus philippii townsendi</i>		X			T/D; Y	20,000 (n/a; 15,830; 2010)	542	≥3.2 ¹⁰
Northern fur seal	<i>Callorhinus ursinus</i>	Pribilof Islands/Eastern Pacific	X			D; Y	637,561 (0.2; 539,638; 2015)	11,602	436
		California	X			-; N	14,050 (n/a; 7,524; 2013)	451	1.8
California sea lion	<i>Zalophus californianus</i>	United States	X	X	X	-; N	296,750 (n/a; 153,337; 2011)	9,200	389
Steller sea lion	<i>Eumetopias jubatus monteriensis</i>	Eastern U.S.	X	X	X	D; Y	41,638 (n/a; 2015)	2,498	108
Family Phocidae (earless seals)									
Harbor seal	<i>Phoca vitulina richardii</i>	California	X			-; N	30,968 (n/a; 27,348; 2012)	1,641	43
		OR/WA Coast ⁸	X	X		-; N	24,732 (0.12; 22,380; 1999)	Undet.	10.6
		Washington Northern Inland Waters ⁸			X	-; N	11,036 (0.15; 7,213; 1999)	Undet.	9.8
		Southern Puget Sound ⁸			X	-; N	1,568 (0.15; 1,025; 1999)	Undet.	3.4

		Hood Canal ⁸			X	-; N	1,088 (0.15; 711; 1999)	Undet.	0.2
Northern elephant seal	<i>Mirounga angustirostris</i>	California Breeding	X		X	-; N	179,000 (n/a; 81,368; 2010)	4,882	8.8

¹Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

²NMFS marine mammal stock assessment reports at: www.nmfs.noaa.gov/pr/sars/. CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable. For three stocks of killer whales, the abundance values represent direct counts of individually identifiable animals; therefore there is only a single abundance estimate with no associated CV. For certain stocks of pinnipeds, abundance estimates are based upon observations of animals (often pups) ashore multiplied by some correction factor derived from knowledge of the species' (or similar species') life history to arrive at a best abundance estimate; therefore, there is no associated CV. In these cases, the minimum abundance may represent actual counts of all animals ashore.

³These values, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, subsistence hunting, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value. All M/SI values are as presented in the draft 2017 SARs (www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports).

⁴Transient and resident killer whales are considered unnamed subspecies (Committee on Taxonomy, 2017).

⁵No information is available to estimate the population size of dwarf sperm whales off the U.S. west coast, as no sightings of this species have been documented despite numerous vessel surveys of this region (Carretta *et al.*, 2017). Dwarf and pygmy sperm whales are difficult to differentiate at sea but, based on previous sighting surveys and historical stranding data, it is thought that recent ship survey sightings were of pygmy sperm whales.

⁶The six species of Mesoplodont beaked whales occurring in the CCE are managed as a single stock due to the rarity of records and the difficulty in distinguishing these animals to species in the field. Based on bycatch and stranding records, it appears that *M. carlhubbsi* is the most commonly encountered of these species (Carretta *et al.*, 2008; Moore and Barlow, 2013). Additional managed stocks in the Pacific include *M. stejnegeri* in Alaskan waters and *M. densirostris* in Hawaiian waters.

⁷The abundance estimate for this stock includes only animals from the "inner coast" population occurring in inside waters of southeastern Alaska, British Columbia, and Washington – excluding animals from the "outer coast" subpopulation, including animals from California – and therefore should be considered a minimum count. For comparison, the previous abundance estimate for this stock, including counts of animals from California that are now considered outdated, was 354.

⁸Abundance estimates for these stocks are not considered current. PBR is therefore considered undetermined for these stocks, as there is no current minimum abundance estimate for use in calculation. We nevertheless present the most recent abundance estimates, as these represent the best available information for use in this document.

⁹These stocks are known to spend a portion of their time outside the U.S. EEZ. Therefore, the PBR presented here is the allocation for U.S. waters only and is a portion of the total. Annual M/SI presented for these species is for U.S. waters only.

¹⁰This represents annual M/SI in U.S. waters. However, the vast majority of M/SI for this stock – the level of which is unknown – would likely occur in Mexican waters.

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Prior to 2016, humpback whales were listed under the ESA as an endangered species worldwide. Following a 2015 global status review (Bettridge *et al.*, 2015), NMFS established 14 distinct population segments (DPS) with different listing statuses (81 FR 62259; September 8, 2016) pursuant to the ESA. The DPSs that occur in U.S. waters do

not necessarily equate to the existing stocks designated under the MMPA and shown in Table 1. Because MMPA stocks cannot be portioned, *i.e.*, parts managed as ESA-listed while other parts managed as not ESA-listed, until such time as the MMPA stock delineations are reviewed in light of the DPS designations, NMFS considers the existing humpback whale stocks under

the MMPA to be endangered and depleted for MMPA management purposes (e.g., selection of a recovery factor, stock status). Within U.S. west coast waters, three current DPSs may occur: The Hawaii DPS (not listed), Mexico DPS (threatened), and Central America DPS (endangered).

Potential Effects of the Specified Activity on Marine Mammals and Their Habitat

We provided a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat in our notice of proposed rulemaking (81 FR 38516; June 13, 2016). Specifically, we considered potential effects to marine mammals from ship strike, physical interaction with various gear types, use of active acoustic sources, and visual disturbance of pinnipeds, as well as effects to prey species and to acoustic habitat. The information is not reprinted here.

Estimated Take by Incidental Harassment, Serious Injury, or Mortality

Except with respect to certain activities not pertinent here, the MMPA defines “harassment” as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment). Serious injury means any injury that will likely result in mortality (50 CFR 216.3).

Take of marine mammals incidental to NWFSC research activities could occur as a result of (1) injury or mortality due to gear interaction (Level A harassment, serious injury, or mortality); (2) behavioral disturbance resulting from the use of active acoustic sources (Level B harassment only); or (3) behavioral disturbance of pinnipeds resulting from incidental approach of researchers (Level B harassment only).

Estimated Take Due to Gear Interaction

Historical Interactions—In order to estimate the number of potential incidents of take that could occur by M/SI through gear interaction, we first considered NWFSC’s record of past such incidents, and then considered in addition other species that may have similar vulnerabilities to NWFSC trawl gear as those species for which we have historical interaction records. Historical interactions with NWFSC research gear were described in Table 4 of our notice of proposed rulemaking (81 FR 38516; June 13, 2016). Please see that document for more information. Available records are for the years 1999 through present. All historical interactions have taken place in the CCRA, offshore Washington and Oregon, and have occurred during use of the Nordic 264 surface trawl net, with a few exceptions. There is one historical interaction in the PSRA (also using the Nordic 264 surface trawl), and one CCRA historical interaction using the modified Cobb midwater trawl. NWFSC has no historical interactions for any bottom trawl, hook and line, or seine gear, and has no historical interactions in the LCRRA. Please see Figure 6–1 in the NWFSC request for authorization for specific locations of these incidents.

Although some historical interactions resulted in the animal(s) being released alive, no serious injury determinations (NMFS, 2012a; 2012b) were made, and it is possible that some of these animals later died. In order to use these historical interaction records in a precautionary manner as the basis for the take estimation process, and because we have no specific information to indicate whether any given future interaction might result in M/SI versus Level A harassment, we conservatively assume that all interactions equate to mortality. Over the past seventeen years, NWFSC has had only infrequent interactions with marine mammals, with 0.1–0.5 animals captured per year

for the pinniped species and 1.4 animals captured per year for the Pacific white-sided dolphin. No Steller sea lion has been captured since 2002, northern fur seals have been involved in only one incident (none since 2000), and only a few California sea lions and harbor seals have been involved in interactions with research fishing gear. However, we assume that any of these species could be captured in any year.

In order to produce the most precautionary take estimates possible, we consider all of the data available to us (*i.e.*, since 1999). In consideration of these interaction records, we assume that one individual of each species of otariid pinniped could be captured per year over the course of the five-year period of validity for these proposed regulations, that two individual harbor seals could be captured per year, and that the worst case event could happen each year for Pacific white-sided dolphins (*i.e.*, six dolphins could be captured in a single trawl in each year). Table 2 shows the projected five-year total captures of these five species for this final rule, as described above, for trawl gear only. Although more than one individual of the two sea lion species has been captured in a single tow, interactions with these species have historically occurred only infrequently, and we believe that the above assumption appropriately reflects the likely total number of individuals involved in research gear interactions over a five-year period. We assume that two total harbor seals could be captured per year in recognition of the demonstrated vulnerability to capture in the PSRA (all other species have been captured only in the CCRA). These estimates are based on the assumption that annual effort (*e.g.*, total annual trawl tow time) over the five-year authorization period will not exceed the annual effort during prior years for which we have interaction records.

TABLE 2—PROJECTED FIVE-YEAR TOTAL TAKE IN TRAWL GEAR FOR HISTORICALLY CAPTURED SPECIES

Gear	Species	CCRA average annual take (total)	PSRA average annual take (total)	Projected 5-year total ¹
Trawl	Pacific white-sided dolphin	6 (30)	30
	California sea lion	1 (5)	5
	Harbor seal	1 (5)	1 (5)	10
	Northern fur seal	1 (5)	5
	Steller sea lion	1 (5)	5

¹ Because there are no historical take records from the LCRRA, we incorporate all projected LCRRA takes in Table 3 below.

In order to estimate the total potential number of incidents of M/SI that could occur incidental to the NWFSC’s use of trawl, hook and line, and seine gear over the five-year period of validity for these

regulations (*i.e.*, takes additional to those described in Table 4 of our notice of proposed rulemaking (81 FR 38516; June 13, 2016)), we first considered whether there are additional species

that may have similar vulnerability to capture in trawl gear as the five species described above that have been taken historically and then evaluate the

potential vulnerability of these and other species to additional gears.

In order to evaluate the potential vulnerability of additional species to trawl and of all species to hook and line and seine gear, we first consulted NMFS's List of Fisheries (LOF), which classifies U.S. commercial fisheries into one of three categories according to the level of incidental marine mammal M/SI that is known to occur on an annual basis over the most recent five-year period (generally) for which data has been analyzed. We provided this information, as presented in the 2015 LOF (79 FR 77919; December 29, 2014), in Table 6 of our notice of proposed rulemaking (81 FR 38516; June 13, 2016) and do not reproduce it here.

Information related to incidental M/SI in relevant commercial fisheries is not, however, the sole determinant of whether it may be appropriate to authorize M/SI incidental to NWFSC survey operations. A number of factors (e.g., species-specific knowledge regarding animal behavior, overall abundance in the geographic region, density relative to NWFSC survey effort, feeding ecology, propensity to travel in groups commonly associated with other species historically taken) were taken into account by the NWFSC to determine whether a species may have a similar vulnerability to certain types of gear as historically taken species. In some cases, we have determined that species without documented M/SI may nevertheless be vulnerable to capture in NWFSC research gear. Similarly, we have determined that some species groups with documented M/SI are not likely to be vulnerable to capture in NWFSC gear. In these instances, we provide further explanation below. Those species with no records of historical interaction with NWFSC research gear and no documented M/SI in relevant commercial fisheries, and for which the NWFSC has not requested the authorization of incidental take, are not considered further in this section. The NWFSC believes generally that any sex or age class of those species for which take authorization is requested could be captured.

In order to estimate a number of individuals that could potentially be captured in NWFSC research gear for those species not historically captured, we first determine which species may have vulnerability to capture in a given gear. Of those species, we then determine whether any may have similar propensity to capture in a given gear as a historically captured species. These species are limited to a few delphinid species that we believe may have similar risk of capture as that

displayed by the Pacific white-sided dolphin. For these species, we assume it is possible that a worst-case scenario of take could occur while at the same time contending that, absent significant range shifts or changes in habitat usage, capture of a species not historically captured would likely be a very rare event. The former assumption also accounts for the likelihood that, for species that often travel in groups, an incident involving capture of that species is likely to involve more than one individual.

For example, we believe that the Risso's dolphin is potentially vulnerable to capture in trawl gear and may have similar propensity to capture in that gear as does the Pacific white-sided dolphin. Because the greatest number of Pacific white-sided dolphins captured in any one trawl tow was six individuals, we assume that six Risso's dolphins could also be captured in a single incident. However, in recognition of the fact that any incident involving the capture of Risso's dolphins would likely be a rare event, we propose a total take authorization over the five-year period of the number that may result from a single, worst-case incident (six dolphins). While we do not necessarily believe that six Risso's dolphins would be captured in a single incident—and that more capture incidents involving fewer individuals could occur, as opposed to a single, worst-case incident—we believe that this is a reasonable approach to estimating potential incidents of M/SI while balancing what could happen in a worst-case scenario with the potential likelihood that no incidents of capture would actually occur. The SWFSC historical capture of northern right whale dolphins in 2008 provides an instructive example of a situation where a worst-case scenario (six dolphins captured in a single trawl tow) did occur, but overall capture of this species was very rare (no other capture incidents before or since).

Separately, for those species that we believe may have a vulnerability to capture in given gear but that we do not believe may have a similar propensity to capture in that gear as a historically-captured species, we assume that capture would be a rare event such that authorization of a single take over the five-year period is likely sufficient to capture the risk of interaction. For example, from the LOF we infer vulnerability to capture in trawl gear for the Dall's porpoise but do not believe that this species has a similar propensity for interaction in trawl gear as the Pacific white-sided dolphin.

Trawl: From the LOF and SWFSC historical gear interactions, we infer vulnerability to trawl gear in the CCRA for the Risso's dolphin, short- and long-beaked common dolphins, northern right whale dolphin, Dall's porpoise, harbor porpoise, and bottlenose dolphin (offshore stock only; NWFSC research has very little overlap with the distribution of the coastal stock of bottlenose dolphin). We consider some of these species to have a similar propensity for interaction with trawl gear as that demonstrated by the Pacific white-sided dolphin (Risso's dolphin, northern right whale dolphin) and the rest to have lower risk of interaction.

Due to their likely presence in the relevant areas and inference based on historical interactions and the LOF, we assume additional vulnerability and therefore potential take for some of these species in trawl gear used in the PSRA and LCRRRA. In the PSRA, these include the harbor porpoise, Dall's porpoise, California sea lion, and Steller sea lion. In the LCRRRA these include the harbor porpoise, harbor seal, California sea lion, and Steller sea lion.

For the striped dolphin, we believe that there is a reasonable likelihood of incidental take in trawl gear although there are no records of incidental M/SI in relevant commercial fisheries. The proposed take authorization for this species was determined to be appropriate based on analogy to other similar species that have been taken either in NWFSC operations or in analogous commercial fishery operations. We believe that the striped dolphin has a similar propensity for interaction with trawl gear as that demonstrated by the Pacific white-sided dolphin.

It is also possible that a captured animal may not be able to be identified to species with certainty. Certain pinnipeds and small cetaceans are difficult to differentiate at sea, especially in low-light situations or when a quick release is necessary. For example, a captured delphinid that is struggling in the net may escape or be freed before positive identification is made. This is only likely to occur in the CCRA due to the greater diversity of pinniped and small cetacean species likely to be encountered in that area. Therefore, the NWFSC has requested the authorization of incidental M/SI for one unidentified pinniped and one unidentified small cetacean over the course of the five-year period of proposed authorization.

Hook and line: The process is the same as is described above for trawl gear. From the LOF and SWFSC historical interactions, we infer

vulnerability to hook and line gear in the CCRA for the Risso's dolphin, bottlenose dolphin, striped dolphin, pygmy and dwarf sperm whale (*i.e.*, *Kogia* spp.), short- and long-beaked common dolphins, short-finned pilot whale, and California and Steller sea lions.

Due to their likely presence in the relevant areas and inference based on historical interactions and the LOF, we assume additional vulnerability and therefore potential take for some of these species in hook and line gear used in the PSRA (hook and line gear is not used in the LCRRA). These include the California sea lion and harbor seal.

Seine: The process is the same as is described above for trawl gear. From the LOF, we infer vulnerability to seine and tangle net gear in the CCRA and/or LCRRA for the short-beaked common dolphin, harbor seal, and California sea lion. Long-beaked common dolphin is

not included because they are much rarer in Oregon and Washington where seine surveys are conducted. Seine gear is used infrequently in the PSRA (*e.g.*, twelve purse seine sets per year) and the move-on rule applied if any small cetacean is seen within 500 m of the planned set. We do not believe that any take in seine gear is likely in the PSRA.

We also believe that there is a reasonable potential of seine gear interaction for a number of species in the CCRA and/or LCRRA for which there are no LOF records of interaction in commercial fisheries gears. These authorizations reflect the NWFSC's expert judgment regarding the distribution of these species in relation to NWFSC use of seine gear offshore Oregon and Washington. For example, several of these species have the potential to interact with NWFSC purse seine surveys in the Columbia River plume, where there are no

corresponding commercial seine fisheries. Therefore, we would not expect the LOF to adequately reflect the risk of marine mammal interaction posed by NWFSC survey activities. Species for which we authorize take in seine gear in the CCRA and/or LCRRA with no LOF interaction records include the Dall's porpoise, Pacific white-sided dolphin, Risso's dolphin, northern right whale dolphin, Steller sea lion, and harbor porpoise. For the harbor porpoise, we expect that there is greater vulnerability to take in these gears (*i.e.*, we expect it could be taken in both the CCRA and LCRRA) and have increased the take authorization relative to the other species accordingly. NWFSC considers the delphinid species to be at risk because of their occurrence in coastal waters offshore Oregon and Washington, and because they often occur in mixed schools and could be caught together in purse seines.

TABLE 3—TOTAL ESTIMATED M/SI DUE TO GEAR INTERACTION, 2018–23

Species	Estimated 5-year total, trawl ¹	Estimated 5-year total, hook and line ¹	Estimated 5-year total, seine ¹	Total, all gears
<i>Kogia</i> spp. ²	1	1
Bottlenose dolphin ³	1	1	2
Striped dolphin	6	1	7
Short-beaked common dolphin	1	1	1	3
Long-beaked common dolphin	1	1	2
Pacific white-sided dolphin	30	1	31
Northern right whale dolphin	6	1	7
Risso's dolphin	6	1	1	8
Short-finned pilot whale	1	1
Harbor porpoise ⁴	3 (CCRA/PSRA/LCRRA)	2 (CCRA/LCRRA)	5
Dall's porpoise	2 (CCRA/PSRA)	1	3
Northern fur seal ⁵	5	5
California sea lion	7 (5 CCRA/PSRA/LCRRA)	2 (CCRA/PSRA)	1 (LCRRA)	10
Steller sea lion	7 (5 CCRA/PSRA/LCRRA)	1	1 (LCRRA)	9
Harbor seal ⁴	11 (5 CCRA/5 PSRA/LCRRA)	1 (PSRA)	1 (LCRRA)	13
Unidentified pinniped	1	1
Unidentified small cetacean	1	1

¹ Please see our notice of proposed rulemaking (81 FR 38516; June 13, 2016) for full detail related to derivation of these take estimates. Takes proposed for authorization are not specific to any area, but our estimates are informed by area-specific vulnerability. All takes are expected to occur in the CCRA, except where the gear-specific breakdown of expected takes per area is provided. Note that hook and line surveys are not proposed for LCRRA and only limited seine surveys are proposed for PSRA.

² We expect that only one *Kogia* spp. may be taken over the five-year timespan and that it could be either a pygmy or dwarf sperm whale.

³ Incidental take is expected only from the offshore stock.

⁴ Incidental take for these species may be of animals from any stock in California, Oregon, or Washington, but expected vulnerability may be assigned to CCE or Washington inland waters stocks according to the expected take proportions shown.

⁵ Incidental take may be of animals from either the eastern Pacific or California stock.

Estimated Take Due to Acoustic Harassment

As described in our notice of proposed rulemaking (81 FR 38516; June 13, 2016; "Potential Effects of the Specified Activity on Marine Mammals"), we believe that NWFSC use of active acoustic sources has, at most, the potential to cause Level B harassment of marine mammals. In order to attempt to quantify the potential for Level B harassment to occur, NMFS (including the NWFSC and acoustics experts from other parts of NMFS) developed an analytical

framework considering characteristics of the active acoustic systems described in our notice of proposed rulemaking (81 FR 38516; June 13, 2016) under *Description of Active Acoustic Sound Sources*, their expected patterns of use, and characteristics of the marine mammal species that may interact with them. We believe that this quantitative assessment benefits from its simplicity and consistency with current NMFS acoustic guidance regarding Level B harassment but caution that, based on a number of deliberately precautionary assumptions, the resulting take estimates may be seen as an

overestimate of the potential for behavioral harassment to occur as a result of the operation of these systems.

In 2016, NMFS released updated "Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing" with revised metrics and thresholds to assess the potential for injury (*e.g.*, permanent threshold shift) from acoustic sources. While the NWFSC's EA and our proposed rule refer to NMFS's historic guidelines, as the documents were completed prior to the recent release of the technical guidance, the conclusions regarding the potential for injury remain

the same. Most importantly, the technical guidance now explicitly takes into account the duration of the sound through the use of the sound exposure level (SEL) metric, as opposed to the previous use of rms sound pressure level (SPL). The effect of this different metric, in particular for the very short duration sounds used for these echosounders, is to largely reduce the exposure level of sound an animal is exposed to for short duration sounds (e.g., for a 1 millisecond ping, an SPL source level is reduced by 30 dB in the SEL metric) offsetting changes in the thresholds themselves. While energy is accumulated over time using SEL, the previous conclusion that an individual would have to remain exceptionally close to a sound source for unrealistic lengths of time holds, suggesting the likelihood of injury occurring is exceedingly small and is therefore not considered further in this analysis.

The operating frequencies of active acoustic systems used by NWFSC sources only go down to 27–33 kHz for the trawl monitoring system, which is not one of the predominant sources, and to 38 kHz for the EK60 echosounder (see Tables 2 and 8 from our notice of proposed rulemaking (81 FR 38516; June 13, 2016)). These frequencies are above the hearing range of baleen whales (*i.e.*, mysticetes); therefore, baleen whales would not be expected to perceive signals from NWFSC active acoustic sources. We would not expect

any exposures to these signals to result in behavioral harassment. Baleen whales are not considered further in this section.

The assessment paradigm for active acoustic sources used in NWFSC fisheries research is relatively straightforward and has a number of key simplifying assumptions. NMFS's current acoustic guidance requires in most cases that we assume Level B harassment occurs when a marine mammal receives an acoustic signal at or above a simple step-function threshold. For use of these active acoustic systems, the appropriate threshold is 160 dB re 1 μ Pa (rms). Estimating the number of exposures at the specified received level requires several determinations, each of which is described sequentially below:

(1) A detailed characterization of the acoustic characteristics of the effective sound source or sources in operation;

(2) The operational areas exposed to levels at or above those associated with Level B harassment when these sources are in operation;

(3) A method for quantifying the resulting sound fields around these sources; and

(4) An estimate of the average density for marine mammal species in each area of operation.

Quantifying the spatial and temporal dimension of the sound exposure footprint (or "swath width") of the active acoustic devices in operation on

moving vessels and their relationship to the average density of marine mammals enables a quantitative estimate of the number of individuals for which sound levels exceed the relevant threshold for each area. The number of potential incidents of Level B harassment is ultimately estimated as the product of the volume of water ensonified at 160 dB rms or higher and the volumetric density of animals determined from simple assumptions about their vertical stratification in the water column. Specifically, reasonable assumptions based on what is known about diving behavior across different marine mammal species were made to segregate those that predominately remain in the upper 200 m of the water column versus those that regularly dive deeper during foraging and transit. We described the approach used (including methods for estimating each of the calculations described above) and the assumptions made that result in conservative estimates in significant detail in our notice of proposed rulemaking (81 FR 38516; June 13, 2016). There have been no changes made to the approach, the informational inputs, or the results. Therefore, we do not repeat the discussion here and refer the reader to the proposed rule. Summaries of the results are provided in Table 4 below. Note that NWFSC only uses active acoustic systems for data acquisition purposes in the CCRA, not in the LCRRA or PSRA.

TABLE 4—DENSITIES AND ESTIMATED SOURCE-, STRATUM-, AND SPECIES-SPECIFIC ANNUAL ESTIMATES OF LEVEL B HARASSMENT

Species	Shallow	Deep	Area density (animals/ km ²) ¹	Volumetric density (animals/ km ³) ²	Estimated Level B harassment, 0–200 m			Estimated Level B harassment, >200 m		Total
					EK60	ME70	SX90	EK60	SX90	
Sperm whale		X	0.002	0.003	1	0	1	3	1	6
<i>Kogia</i> spp		X	0.001	0.002	0	0	1	2	0	3
Cuvier's beaked whale		X	0.004	0.008	2	1	2	7	2	14
Baird's beaked whale		X	0.001	0.002	0	0	1	2	0	3
Mesoplodont beaked whales		X	0.001	0.002	0	0	1	2	0	3
Bottlenose dolphin	X		0.002	0.009	2	1	3	0	0	6
Striped dolphin	X		0.017	0.083	18	6	25	0	0	49
Long-beaked common dolphin	X		0.019	0.096	20	7	28	0	0	55
Short-beaked common dolphin	X		0.309	1.547	325	115	455	0	0	895
Pacific white-sided dolphin	X		0.021	0.105	22	8	31	0	0	61
Northern right whale dolphin	X		0.010	0.049	10	4	14	0	0	28
Risso's dolphin	X		0.010	0.052	11	4	15	0	0	30
Killer whale	X		0.001	0.004	1	0	1	0	0	2
Short-finned pilot whale		X	0.0003	0.001	0	0	0	1	0	1
Harbor porpoise	X		⁴ 0.038	0.189	40	14	56	0	0	110
Dall's porpoise	X		0.076	0.378	79	28	111	0	0	218
Guadalupe fur seal	X		³ 0.007	0.037	8	3	11	0	0	22
Northern fur seal	X		³ 0.649	3.245	682	241	955	0	0	1,878
California sea lion	X		³ 0.297	1.484	312	110	437	0	0	859
Steller sea lion	X		³ 0.060	0.301	63	22	89	0	0	174
Harbor seal	X		³ 0.056	0.279	59	21	82	0	0	162
Northern elephant seal		X	³ 0.179	0.358	75	27	105	336	79	622

¹ All density estimates from Barlow and Forney (2007) unless otherwise indicated.

² Volumetric density estimates derived by dividing area density estimates by 0.2 km (for shallow species) or 0.5 km (for deep species), corresponding with defined depth strata.

³ Density estimates derived by NWFSC from SAR abundance estimates and notional study area of 1,000,000 km².

⁴ ManTech-SRS Technologies (2007) estimated a harbor porpoise density for coastal and inland waters of Washington, which is used as the best available proxy here. There are no known density estimates for harbor porpoises in NWFSC survey areas in the CCRA.

Estimated Take Due to Physical Disturbance

Estimated take due to physical disturbance could potentially happen in the PSRA and LCRRA, and would result in no greater than Level B harassment.

It is likely that some pinnipeds will move or flush from known haulouts into the water in response to the presence or sound of NWFSC vessels or researchers, as a result of unintentional approach during survey activity. Behavioral

responses may be considered according to the scale shown in Table 5 and based on the method developed by Mortenson (1996). We consider responses corresponding to Levels 2–3 to constitute Level B harassment.

TABLE 5—SEAL RESPONSE TO DISTURBANCE

Level	Type of response	Definition
1	Alert	Seal head orientation or brief movement in response to disturbance, which may include turning head towards the disturbance, craning head and neck while holding the body rigid in a u-shaped position, changing from a lying to a sitting position, or brief movement of less than twice the animal's body length.
2	Movement	Movements away from the source of disturbance, ranging from short withdrawals at least twice the animal's body length to longer retreats over the beach.
3	Flight	All retreats (flushes) to the water.

The NWFSC has estimated potential incidents of Level B harassment due to physical disturbance (Table 6) by considering the number of seals believed to potentially be present at affected haul-outs and the number of visits expected to be made by NWFSC

researchers. The number of haulouts disturbed and number of animals assumed to be on those haulouts was determined by NWFSC on the basis of anecdotal evidence from researchers. Although not all individuals on “disturbed” haulouts would necessarily

actually be disturbed, and some haulouts may experience some disturbance at distances greater than expected, we believe that this approach is a reasonable effort towards accounting for this potential source of disturbance.

TABLE 6—ESTIMATED ANNUAL LEVEL B HARASSMENT OF PINNIPEDS ASSOCIATED WITH DISTURBANCE BY RESEARCHERS

Species	Location	Estimated total number of animals on potentially disturbed haul-outs	Number of visits per year	Estimated annual Level B harassment
Harbor seal	Puget Sound	1,440	8	11,520
	Columbia River	3,000	25	75,000
California sea lion	Puget Sound	350	8	2,800

Summary of Estimated Incidental Take

Here we provide a summary of the total incidental take authorization on an annual basis, as well other information relevant to the negligible impact analysis. Table 7 shows information relevant to our negligible impact analysis concerning the total annual taking that could occur for each stock from NMFS's scientific research activities when considering incidental take previously authorized for SWFSC (80 FR 58982; September 30, 2015) and take authorized for NWFSC. As footnoted in Table 7, the indicated level of take could occur to any species or stock for those species with multiple stocks (e.g., northern fur seal) or considered as a group (e.g., Mesoplodont beaked whales). However, the harbor porpoise and harbor seal each have multiple stocks spanning the three NWFSC research areas, and we provide further detail regarding our consideration of potential take specific to stocks that may occur in the PSRA and LCRRA. Many stocks do not occur in those research areas and, therefore, would not be vulnerable to interaction with research gear deployed in those areas.

For harbor porpoise, we authorize a total of five takes by M/SI for all stocks

combined over the five-year period of validity for these regulations. For the purposes of the negligible impact analysis, we assume that all of these takes could potentially be in the form of M/SI; PBR is not intended for assessment of the significance of harassment. These takes could occur to any stock; however, our take authorization is informed by reasonable expectation regarding species vulnerability to gear used in the three research areas. Of the five total takes, we expect that two might occur in the CCRA, one in the PSRA, and two in the LCRRA. Therefore, corresponding with the relationship between stock ranges and the location of NWFSC research activities, the likely maximum takes that could accrue to any harbor porpoise stock from California to southern Oregon would be two, while the northern Oregon/Washington coast stock could potentially accrue four takes because it is vulnerable to the takes expected in either the CCRA or LCRRA. In Table 7 below, the total take authorization column reflects the total of four takes that could occur in either the CCRA or LCRRA (and the one take expected in the PSRA, which would occur to the Washington inland waters stock). However, the estimated

maximum annual take column reflects the annualized stock-specific risk, *i.e.*, any stock in the CA-southern OR grouping is expected to be vulnerable to a maximum of two takes over the 5-year period (0.4/year) while the northern OR/WA coast stock could be vulnerable to as many as four takes over the five years (0.8/year). This stock-specific accounting does not change our expectation that a total of five takes would occur for all stocks combined but informs our stock-specific negligible impact analysis.

Similarly, the harbor seal has separate designated stocks that may occur in all three research areas. We will authorize a total of thirteen takes by M/SI for all harbor seal stocks combined, and expect that five of these may occur in the CCRA, six in the PSRA, and two in the LCRRA. Therefore, while we would expect that a maximum of five takes could accrue to the California stock, as many as seven takes could occur for the Oregon/Washington coastal stock (which is the only stock that may occur in the LCRRA). Although NMFS has split the former Washington inland waters stock of harbor seals into three separate stocks, we do not have sufficient information to assess stock-specific risk in the PSRA. Separately,

we have estimated that 162 incidents of acoustic harassment may occur for harbor seals due to NWFSC use of active acoustic systems (in the CCRRA only) and that, due to the physical presence of researchers, individual harbor seals on haulouts (as many as 3,000) may be disturbed up to 25 times per year in the LCRRA. Therefore, as shown in Table 7, the California stock of harbor seals is vulnerable to only the estimated 162 acoustic harassment takes, but the OR/WA coast stock would be vulnerable to both the acoustic harassment takes as well as the physical disturbance takes. However, note that the percent of estimated population is calculated considering the number of individuals

anticipated to be disturbed rather than the number of incidents of disturbance.

We previously authorized take of marine mammals incidental to fisheries research operations conducted by the SWFSC (see 80 FR 58982 and 80 FR 68512). This take would occur to some of the same stocks for which we will authorize take incidental to NWFSC fisheries research operations. Therefore, in order to evaluate the likely impact of the take by M/SI to be authorized pursuant to this rule, we consider not only other ongoing sources of human-caused mortality but the potential mortality authorized for SWFSC. As used in this document, other ongoing sources of human-caused (anthropogenic) mortality refers to

estimates of realized or actual annual mortality reported in the SARs and does not include authorized or unknown mortality. Below, we consider the total taking by M/SI authorized for NWFSC and previously authorized for SWFSC together to produce a maximum annual M/SI take level (including take of unidentified marine mammals that could accrue to any relevant stock) and compare that value to the stock's PBR value, considering ongoing sources of anthropogenic mortality (as described in footnote 4 of Table 7 and in the following discussion). PBR and annual M/SI values considered in Table 7 reflect the most recent information available.

TABLE 7—SUMMARY INFORMATION RELATED TO NWFSC ANNUAL TAKE AUTHORIZATION, 2018–23

Species ¹	Total annual Level B harassment authorization ²	Percent of estimated population abundance	Proposed total M/SI ³ authorization, 2018–23	SWFSC total M/SI authorization, 2015–20	Estimated maximum annual M/SI ⁴	PBR minus annual M/SI (%) ⁵	Stock trend ⁶
Sperm whale	6	0.3	0	0	0	n/a	?
<i>Kogia</i> spp	3	0.1	1	1	0.4	19.2 (2.1)	?
Cuvier's beaked whale	14	0.4	0	0	0	n/a	↓
Baird's beaked whale	3	0.1	0	0	0	n/a	?
Mesoplodont beaked whales	3	0.1	0	0	0	n/a	↓
Bottlenose dolphin (offshore stock).	6	0.3	2	9	2.6	9.4 (27.7)	?
Striped dolphin	49	0.2	7	12	4.2	237.2 (1.8)	?
Long-beaked common dolphin.	55	0.1	2	12	3.2	621.6 (0.5)	↑
Short-beaked common dolphin.	895	0.1	3	12	3.4	8,353 (<0.1) ..	?
Pacific white-sided dolphin ..	61	0.2	31	35	13.6	189.1 (7.2)	?
Northern right whale dolphin	28	0.1	7	10	3.8	175.2 (2.2)	?
Risso's dolphin	30	0.5	8	12	4.4	42.3 (10.4)	?
Killer whale ⁷	2	0.8	0	0	0	n/a	?
Short-finned pilot whale	1	0.1	1	1	0.4	3.3 (12.1)	?
Harbor porpoise (CA-southern OR stocks) ⁷ .	110	3.8	4	5	1.8	20.4 (8.8)	?
Harbor porpoise (Northern OR/WA coast).	2.2	148 (1.5)	?
Harbor porpoise (WA inland waters).	0	n/a	1	0	0.2	58.8 (0.3)	?
Dall's porpoise	218	0.9	3	5	2	171.7 (1.2)	?
Guadalupe fur seal	22	0.1	0	0	0	n/a	↑
Northern fur seal ⁶	⁸ 1,878	0.3	5	5	2.4	449.4 (0.5)	↑
California sea lion	3,659	0.4	10	25	7.6	8,815 (0.1)	↑
Steller sea lion	174	0.4	9	10	4.4	2,390.6 (0.2) ..	↑
Harbor seal (CA)	75,162	0.6	5	9	3.2	1,598.2 (0.2) ..	→
Harbor seal (OR/WA coast)	12.8	2	1.8	Unknown	→
Harbor seal (WA inland waters).	11,520	10.5	6	0	1.2	Unknown	→
Northern elephant seal	622	0.3	5	5	2.2	4,873.2 (0.1) ..	↑
Unidentified small cetacean	n/a	n/a	1	1	n/a	n/a	n/a
Unidentified pinniped	n/a	n/a	1	2	n/a	n/a	n/a

Please see our notice of proposed rulemaking (81 FR 38516; June 13, 2016) for full details.

¹ For species with multiple stocks or for species groups (*Kogia* spp. and Mesoplodont beaked whales), indicated level of take could occur to individuals from any stock or species except as indicated in table.

² Level B harassment totals include estimated take due to acoustic harassment and, for harbor seals and California sea lions, estimated take due to physical disturbance. Active acoustic devices are not used for data acquisition in the PSRA; therefore, no takes by acoustic harassment are expected for stocks that occur entirely or largely in inland waters (e.g., resident killer whales). Takes by physical disturbance for pinniped species represent repeated takes of smaller numbers of individuals (e.g., we expect as many as 1,440 harbor seals in the PSRA to be harassed on as many as eight occasions). The "percent of estimated population" column represents this smaller number of individuals taken rather than the total number of take incidents.

³ As explained earlier in this document, gear interaction could result in mortality, serious injury, or Level A harassment. Because we do not have sufficient information to enable us to parse out these outcomes, we present such take as a pool. For purposes of this negligible impact analysis we assume the worst case scenario (that all such takes result in mortality).

⁴ This column represents the total number of incidents of M/SI that could potentially accrue to the specified species or stock as a result of NMFS' fisheries research activities and is the number carried forward for evaluation in the negligible impact analysis (later in this document). To reach this total, we add one to the total for each pinniped or cetacean that may be captured in trawl gear in the CCRA. This represents the potential that the take of an unidentified pinniped or small cetacean could accrue to any given stock captured in that gear in that area. The take authorization is formulated as a five-year total; the annual average is used only for purposes of negligible impact analysis. We recognize that portions of an animal may not be taken in a given year.

⁵ This value represents the calculated PBR less the average annual estimate of ongoing anthropogenic mortalities (*i.e.*, total annual human-caused M/SI, which is presented in the SARs). For the Pacific-white sided dolphin, harbor seal (California stock), northern fur seal (California stock), Steller sea lion, and California sea lion, we subtract the annual average of mortalities occurring incidental to fisheries research from the total human-caused M/SI prior to calculating this value, as we explicitly account for predicted future mortalities incidental to fisheries research via the estimated maximum annual M/SI column. In parentheses, we provide the estimated maximum annual M/SI expressed as a percentage of this value.

⁶ See relevant SARs for more information regarding stock status and trends. Interannual increases may not be interpreted as evidence of a trend. Based on the most recent abundance estimates, harbor seal stocks may have reached carrying capacity and appear stable. A time series of stock-specific abundance estimates for harbor porpoise shows either increasing or stable estimates, but it is not statistically valid to infer a trend.

⁷ These species have multiple stocks that may be affected. Values for "percent of estimated population" and "PBR—annual M/SI" (where relevant) calculated for the stock with the lowest population abundance and/or PBR (as appropriate). This approach assumes that all indicated takes would accrue to the stock in question, which is a very conservative assumption. Stocks in question are the offshore killer whale, Morro Bay harbor porpoise, and California northern fur seal.

⁸ Calculated on the basis of relative abundance; *i.e.*, of 1,878 total estimated incidents of Level B harassment, we would expect on the basis of relative abundance in the study area that 98 percent would accrue to the Pribilof Islands/Eastern Pacific stock and two percent would accrue to the California stock.

Negligible Impact Analysis and Determination

We received no public comments or new information indicating any deficiencies in our preliminary determinations, as provided in our notice of proposed rulemaking (81 FR 38516; June 13, 2016).

Introduction—NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken" by mortality, serious injury, and Level A or Level B harassment, we consider other factors, such as the likely nature of any behavioral responses (*e.g.*, intensity, duration), the context of any such responses (*e.g.*, critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.*, as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of

human-caused mortality, and specific consideration of take by M/SI previously authorized for other NMFS research activities).

We note here that the takes from potential gear interactions enumerated below could result in non-serious injury, but their worse potential outcome (mortality) is analyzed for the purposes of the negligible impact determination. We discuss here the connection between the mechanisms for authorizing incidental take under section 101(a)(5) for activities, such as NWFS's research activities, and for authorizing incidental take from commercial fisheries. In 1988, Congress amended the MMPA's provisions for addressing incidental take of marine mammals in commercial fishing operations. Congress directed NMFS to develop and recommend a new long-term regime to govern such incidental taking (see MMC, 1994). The need to develop a system suited to the unique circumstances of commercial fishing operations led NMFS to suggest a new conceptual means and associated regulatory framework. That concept, Potential Biological Removal (PBR), and a system for developing plans containing regulatory and voluntary measures to reduce incidental take for fisheries that exceed PBR were incorporated as sections 117 and 118 in the 1994 amendments to the MMPA.

PBR is defined in the MMPA (16 U.S.C. 1362(20)) as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population, and is a measure to be considered when evaluating the effects of M/SI on a marine mammal species or stock. Optimum sustainable population (OSP) is defined by the MMPA (16 U.S.C.

1362(9)) as the number of animals which will result in the maximum productivity of the population or the species, keeping in mind the carrying capacity of the habitat and the health of the ecosystem of which they form a constituent element. A primary goal of the MMPA is to ensure that each species or stock of marine mammal is maintained at or returned to its OSP.

PBR values are calculated by NMFS as the level of annual removal from a stock that will allow that stock to equilibrate within OSP at least 95 percent of the time, and is the product of factors relating to the minimum population estimate of the stock (N_{min}); the productivity rate of the stock at a small population size; and a recovery factor. Determination of appropriate values for these three elements incorporates significant precaution, such that application of the parameter to the management of marine mammal stocks may be reasonably certain to achieve the goals of the MMPA. For example, calculation of N_{min} incorporates the precision and variability associated with abundance information and is intended to provide reasonable assurance that the stock size is equal to or greater than the estimate (Barlow *et al.*, 1995). In general, the three factors are developed on a stock-specific basis in consideration of one another in order to produce conservative PBR values that appropriately account for both imprecision that may be estimated as well as potential bias stemming from lack of knowledge (Wade, 1998).

PBR can be used as a consideration of the effects of M/SI on a marine mammal stock but was applied specifically to work within the management framework for commercial fishing incidental take. PBR cannot be applied appropriately outside of the section 118 regulatory framework for which it was

designed without consideration of how it applies in section 118 and how other statutory management frameworks in the MMPA differ. PBR was not designed as an absolute threshold limiting commercial fisheries, but rather as a means to evaluate the relative impacts of those activities on marine mammal stocks. Even where commercial fishing is causing M/SI at levels that exceed PBR, the fishery is not suspended. When M/SI exceeds PBR, NMFS may develop a take reduction plan, usually with the assistance of a take reduction team. The take reduction plan will include measures to reduce and/or minimize the taking of marine mammals by commercial fisheries to a level below the stock's PBR. That is, where the total annual human-caused M/SI exceeds PBR, NMFS is not required to halt fishing activities contributing to total M/SI but rather utilizes the take reduction process to further mitigate the effects of fishery activities via additional bycatch reduction measures. PBR is not used to grant or deny authorization of commercial fisheries that may incidentally take marine mammals.

Similarly, to the extent consideration of PBR may be relevant to considering the impacts of incidental take from activities other than commercial fisheries, using it as the sole reason to deny incidental take authorization for those activities would be inconsistent with Congress's intent under section 101(a)(5) and the use of PBR under section 118. The standard for authorizing incidental take under section 101(a)(5) continues to be, among other things, whether the total taking will have a negligible impact on the species or stock. When Congress amended the MMPA in 1994 to add section 118 for commercial fishing, it did not alter the standards for authorizing non-commercial fishing incidental take under section 101(a)(5), acknowledging that negligible impact under section 101(a)(5) is a separate standard from PBR under section 118. In fact, in 1994 Congress also amended section 101(a)(5)(E) (a separate provision governing commercial fishing incidental take for species listed under the Endangered Species Act) to add compliance with the new section 118 but kept the requirement for a negligible impact finding, showing that the determination of negligible impact and application of PBR may share certain features but are different.

Since the introduction of PBR, NMFS has used the concept almost entirely within the context of implementing sections 117 and 118 and other commercial fisheries management-related provisions of the MMPA. The

MMPA requires that PBR be estimated in stock assessment reports and that it be used in applications related to the management of take incidental to commercial fisheries (*i.e.*, the take reduction planning process described in section 118 of the MMPA and the determination of whether a stock is "strategic" (16 U.S.C. 1362(19))), but nothing in the MMPA requires the application of PBR outside the management of commercial fisheries interactions with marine mammals.

Nonetheless, NMFS recognizes that as a quantitative metric, PBR may be useful in certain instances as a consideration when evaluating the impacts of other human-caused activities on marine mammal stocks. Outside the commercial fishing context, and in consideration of all known human-caused mortality, PBR can help inform the potential effects of M/SI caused by activities authorized under 101(a)(5)(A) on marine mammal stocks. As noted by NMFS and the USFWS in our implementation regulations for the 1986 amendments to the MMPA (54 FR 40341, September 29, 1989), the Services consider many factors, when available, in making a negligible impact determination, including, but not limited to, the status of the species or stock relative to OSP (if known), whether the recruitment rate for the species or stock is increasing, decreasing, stable, or unknown, the size and distribution of the population, and existing impacts and environmental conditions. To specifically use PBR, along with other factors, to evaluate the effects of M/SI, we first calculate a metric for each species or stock that incorporates information regarding ongoing anthropogenic M/SI into the PBR value (*i.e.*, PBR minus the total annual anthropogenic mortality/serious injury estimate), which is called "residual PBR" (Wood *et al.*, 2012). We then consider how the anticipated potential incidental M/SI from the activities being evaluated compares to residual PBR. Anticipated or potential M/SI that exceeds residual PBR is considered to have a higher likelihood of adversely affecting rates of recruitment or survival, while anticipated M/SI that is equal to or less than residual PBR has a lower likelihood (both examples given without consideration of other types of take, which also factor into a negligible impact determination). In such cases where the anticipated M/SI is near, at, or above residual PBR, consideration of other factors, including those outlined above as well as mitigation and other factors (positive or negative), is especially important to assessing

whether the M/SI will have a negligible impact on the stock. As described above, PBR is a conservative metric and is not intended to be used as a solid cap on mortality—accordingly, impacts from M/SI that exceed residual PBR may still potentially be found to be negligible in light of other factors that offset concern, especially when robust mitigation and adaptive management provisions are included.

Alternately, for a species or stock with incidental M/SI less than 10 percent of residual PBR, we consider M/SI from the specified activities to represent an insignificant incremental increase in ongoing anthropogenic M/SI that alone (*i.e.*, in the absence of any other take) cannot affect annual rates of recruitment and survival. In a prior incidental take rulemaking and in the commercial fishing context, this threshold is identified as the significance threshold, but it is more accurately an insignificance threshold outside commercial fishing because it represents the level at which there is no need to consider other factors in determining the role of M/SI in affecting rates of recruitment and survival. Assuming that any additional incidental take by harassment would not exceed the negligible impact level, the anticipated M/SI caused by the activities being evaluated would have a negligible impact on the species or stock. This 10 percent was identified as a workload simplification consideration to avoid the need to provide unnecessary additional information when the conclusion is relatively obvious, but as described above, values above 10 percent have no particular significance associated with them until and unless they approach residual PBR.

Our evaluation of the M/SI for each of the species and stocks for which mortality could occur follows. In addition, all mortality authorized for some of the same species or stocks over the next several years pursuant to our final rulemaking for the NMFS Southwest Fisheries Science Center has been incorporated into the residual PBR.

We first consider maximum potential incidental M/SI for each stock (Table 7) in consideration of NMFS's threshold for identifying insignificant M/SI take (10 percent of residual PBR (69 FR 43338; July 20, 2004)). By considering the maximum potential incidental M/SI in relation to PBR and ongoing sources of anthropogenic mortality, we begin our evaluation of whether the potential incremental addition of M/SI through NWFSC research activities may affect the species' or stock's annual rates of recruitment or survival. We also consider the interaction of those

mortalities with incidental taking of that species or stock by harassment pursuant to the specified activity.

Analysis—Please see Table 7 for information related to this analysis. The large majority of stocks that may potentially be taken by M/SI (18 of 21) fall below the insignificance threshold, while an additional four stocks do not have current PBR values and therefore are evaluated using other factors. We first consider stocks expected to be affected only by behavioral harassment and those stocks that fall below the insignificance threshold. Next, we consider those stocks above the insignificance threshold (*i.e.*, the offshore stock of bottlenose dolphin, Risso's dolphin, and short-finned pilot whale) and those without PBR values (harbor seals along the Oregon and Washington coasts and in Washington inland waters).

As described in greater depth in our notice of proposed rulemaking (81 FR 38516; June 13, 2016), we do not believe that NWFSC use of active acoustic sources has the likely potential to cause any effect exceeding Level B harassment of marine mammals. In addition, for the majority of species, the annual take by Level B harassment is very low in relation to the population abundance estimate (less than one percent). We have produced what we believe to be precautionary estimates of potential incidents of Level B harassment. The procedure for producing these estimates, described in detail in our notice of proposed rulemaking (81 FR 38516; June 13, 2016), represents NMFS's best effort towards balancing the need to quantify the potential for occurrence of Level B harassment due to production of underwater sound with a general lack of information related to the specific way that these acoustic signals, which are generally highly directional and transient, interact with the physical environment and to a meaningful understanding of marine mammal perception of these signals and occurrence in the areas where NWFSC operates. The sources considered here have moderate to high output frequencies (10 to 180 kHz), generally short ping durations, and are typically focused (highly directional) to serve their intended purpose of mapping specific objects, depths, or environmental features. In addition, some of these sources can be operated in different output modes (*e.g.*, energy can be distributed among multiple output beams) that may lessen the likelihood of perception by and potential impacts on marine mammals in comparison with the quantitative

estimates that guide our proposed take authorization.

In addition, otariid pinnipeds are less likely than other taxa to perceive acoustic signals generated by NWFSC or, given perception, to react to these signals than the quantitative estimates indicate. This group of pinnipeds has reduced functional hearing at the higher frequencies produced by active acoustic sources considered here (*e.g.*, primary operating frequencies of 40–180 kHz) and, based purely on their auditory capabilities, the potential impacts are likely much less than we have calculated as these relevant factors are not taken into account.

As described previously, there is some minimal potential for temporary effects to hearing for certain marine mammals, but most effects would likely be limited to temporary behavioral disturbance. Effects on individuals that are taken by Level B harassment will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring), reactions that are considered to be of low severity (*e.g.*, Ellison *et al.*, 2012). Individuals may move away from the source if disturbed, but because the source is itself moving and because of the directional nature of the sources considered here, there is unlikely to be even temporary displacement from areas of significance and any disturbance would be of short duration. Although there is no information on which to base any distinction between incidents of harassment and individuals harassed, the same factors, in conjunction with the fact that NWFSC survey effort is widely dispersed in space and time, indicate that repeated exposures of the same individuals would be very unlikely. For these reasons, we do not consider the level of take by acoustic disturbance to represent a significant additional population stressor when considered in context with the proposed level of take by M/SI for any species.

Similarly, disturbance of pinnipeds on haulouts by researchers approaching on foot or in small vessels (as is expected for harbor seals in the lower Columbia River and Puget Sound and for California sea lions in Puget Sound) are expected to be infrequent and cause only a temporary disturbance on the order of minutes. As noted previously, monitoring results from other activities involving the disturbance of pinnipeds and relevant studies of pinniped populations that experience more regular vessel disturbance indicate that individually significant or population level impacts are unlikely to occur. When considering the individual

animals likely affected by this disturbance, only a small fraction (less than fifteen percent) of the estimated population abundance of the affected stocks would be expected to experience the disturbance.

As noted above, authorized M/SI above the insignificance threshold does not necessarily indicate that the take is unsustainable or that it may constitute more than a negligible impact. Rather, we simply use this metric as a guide to indicate when further evaluation of the available information is warranted. For the offshore stock of bottlenose dolphin, Risso's dolphin, and short-finned pilot whale, maximum total potential M/SI due to NMFS's fisheries research activity (SWFSC and NWFSC combined), while above the insignificance threshold, is low relative to residual PBR (approximately 28, 10, and 12 percent, respectively).

The only known source of other anthropogenic mortality for the offshore stock of bottlenose dolphin and the Risso's dolphin is in commercial fisheries, and such take is considered to be insignificant and approaching zero mortality and serious injury. Therefore, there is no information to suggest that the incremental additional removals due to NWFSC fisheries research cause any concern with regard to annual rates of recruitment or survival for these stocks.

Similarly, commercial fisheries provide the only known cause of anthropogenic mortality for the short-finned pilot whale. However, due to the relatively low PBR value for this stock, such take cannot be considered to be insignificant and approaching zero mortality and serious injury. The only takes in commercial fisheries from 2010–14 were due to interactions with the California drift gillnet fishery, and occurred only in 2014. Therefore, it is unclear that these fishery takes will constitute an ongoing source of mortality and, regardless, any level of removals up to PBR could occur while still allowing the stock to reach or maintain its optimum sustainable population, as indicated in the definition of the PBR metric. The available information, *i.e.*, that there is only one other source of anthropogenic mortality, which has resulted in a low level of mortalities in one year and may not be an ongoing source of mortality, and that the authorized take is low compared to residual PBR (10 percent), indicates that there is no concern regarding the impacts of incremental additional removals due to NWFSC fisheries research on annual rates of recruitment or survival for this stock. Nevertheless, if bycatch in commercial fisheries increases, or other sources of

mortality are recorded for this stock, we will use the adaptive management provisions of these regulations to prescribe increased mitigation sufficient to reduce the likelihood of incidental take in NMFS fisheries research activities. No population trends are known for these three stocks.

PBR is unknown for harbor seals on the Oregon and Washington coasts and in Washington inland waters (comprised of the Hood Canal, southern Puget Sound, and Washington northern inland waters stocks). The Hood Canal, southern Puget Sound, and Washington northern inland waters stocks were formerly a single inland waters stock. Both the Oregon/Washington coast and Washington inland waters stocks of harbor seal were considered to be stable following the most recent abundance estimates (in 1999, stock abundances were estimated at 24,732 and 13,692, respectively). However, a Washington Department of Fish and Wildlife expert (S. Jeffries) stated an unofficial abundance of 32,000 harbor seals in Washington (Mapes, 2013). Therefore, it is reasonable to assume that at worst, the stocks have not declined since the last abundance estimates. Ongoing anthropogenic mortality is estimated at 10.6 harbor seals per year for the coastal stock and 13.4 for inland waters seals; therefore, we reasonably assume that the maximum potential annual M/SI incidental to NMFS's fisheries research activities (1.8 and 1.2, respectively) is a small fraction of any sustainable take level that might be calculated for either stock. For the reasons stated above, we do not consider the level of take by acoustic and physical disturbance for harbor seals to represent a significant additional population stressor when considered in context with the proposed level of take by M/SI.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the planned mitigation measures, we find that the total marine mammal take from NWFSC's fisheries research activities will have a negligible impact on the affected marine mammal species or stocks. In summary, this finding of negligible impact is founded on the following factors: (1) The possibility of injury, serious injury, or mortality from the use of active acoustic devices may reasonably be considered discountable; (2) the anticipated incidents of Level B harassment from the use of active acoustic devices and physical disturbance of pinnipeds consist of, at worst, temporary and relatively minor modifications in behavior; (3) the

predicted number of incidents of potential mortality are at insignificant levels (*i.e.*, below ten percent of residual PBR) for a majority of affected stocks; (4) consideration of additional factors for the Risso's dolphin, offshore stock of bottlenose dolphin, and short-finned pilot whale do not reveal cause for concern; (5) available information regarding two harbor seal stocks indicates that total maximum potential M/SI is sustainable; and (6) the presumed efficacy of the planned mitigation measures in reducing the effects of the specified activity to the level of least practicable adverse impact. In addition, no M/SI is authorized for any species or stock that is listed under the ESA or considered depleted under the MMPA. In combination, we believe that these factors demonstrate that the specified activity will have only short-term effects on individuals (resulting from Level B harassment) and that the total level of taking will not impact rates of recruitment or survival sufficiently to result in population-level impacts.

Small Numbers Analysis

Please see Table 7 for information relating to this small numbers analysis. The total amount of taking authorized is less than one percent for a large majority of stocks. The total amount of taking for remaining stocks ranges from four to thirteen percent.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed mitigation measures, we find that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Monitoring and Reporting

In order to issue an incidental take authorization for an activity, section 101(a)(5)(A) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for incidental take authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area.

Any monitoring requirement we prescribe should improve our understanding of one or more of the following:

- Occurrence of marine mammal species in action area (*e.g.*, presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.*, source characterization, propagation, ambient noise); (2) affected species (*e.g.*, life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.*, age, calving, or feeding areas);
- Individual responses to acute stressors, or impacts of chronic exposures (behavioral or physiological);
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of an individual; or (2) population, species, or stock;
- Effects on marine mammal habitat and resultant impacts to marine mammals; and
- Mitigation and monitoring effectiveness.

NWFSC plans to make more systematic its training, operations, data collection, animal handling and sampling protocols, etc., in order to improve its ability to understand how mitigation measures influence interaction rates and ensure its research operations are conducted in an informed manner and consistent with lessons learned from those with experience operating these gears in close proximity to marine mammals. It is in this spirit that the monitoring requirements described below were crafted.

Visual Monitoring

Marine mammal watches are a standard part of conducting fisheries research activities, and are implemented as described previously in "Mitigation." Dedicated marine mammal visual monitoring occurs as described (1) for some period prior to deployment of most research gear; (2) throughout deployment and active fishing of all research gears; (3) for some period prior to retrieval of longline gear; and (4) throughout retrieval of all research gear. This visual monitoring is performed by trained NWFSC personnel with no other responsibilities during the monitoring period. Observers record the species and estimated number of animals present and their behaviors, which may be valuable information towards an understanding of whether certain species may be attracted to vessels or certain survey gears. Separately, marine mammal watches are conducted by watch-standers (those navigating the

vessel and other crew; these will typically not be NWFSC personnel) at all times when the vessel is being operated. The primary focus for this type of watch is to avoid striking marine mammals and to generally avoid navigational hazards. These watchstanders typically have other duties associated with navigation and other vessel operations and are not required to record or report to the scientific party data on marine mammal sightings, except when gear is being deployed or retrieved.

In the PSRA and LCRRA only, the NWFSC will monitor any potential disturbance of hauled-out pinnipeds, paying particular attention to the distance at which different species of pinniped are disturbed. Disturbance will be recorded according to the three-point scale, representing increasing seal response to disturbance, shown in Table 5.

Training

NWFSC anticipates that additional information on practices to avoid marine mammal interactions can be gleaned from training sessions and more systematic data collection standards. The NWFSC will conduct annual trainings for all CSs and other personnel who may be responsible for conducting dedicated marine mammal visual observations to explain mitigation measures and monitoring and reporting requirements, mitigation and monitoring protocols, marine mammal identification, recording of count and disturbance observations, completion of datasheets, and use of equipment. Some of these topics may be familiar to NWFSC staff, who may be professional biologists. The NWFSC shall determine the agenda for these trainings and ensure that all relevant staff have necessary familiarity with these topics. The first such training will include three primary elements:

First, the course will provide an overview of the purpose and need for the authorization, including mandatory mitigation measures by gear and the purpose for each, and species that NWFSC is authorized to incidentally take.

Second, the training will provide detailed descriptions of reporting, data collection, and sampling protocols. This portion of the training will include instruction on how to complete new data collection forms such as the marine mammal watch log, the incidental take form (e.g., specific gear configuration and details relevant to an interaction with protected species), and forms used for species identification and biological sampling. The biological data collection

and sampling training module will include the same sampling and necropsy training that is used for the West Coast Regional Observer training.

Third, NWFSC will also dedicate a portion of training to discussion of best professional judgment (which is recognized as an integral component of mitigation implementation; see “Mitigation”), including use in any incidents of marine mammal interaction and instructive examples where use of best professional judgment was determined to be successful or unsuccessful. We recognize that many factors come into play regarding decision-making at sea and that it is not practicable to simplify what are inherently variable and complex situational decisions into rules that may be defined on paper. However, it is our intent that use of best professional judgment be an iterative process from year to year, in which any at-sea decision-maker (i.e., responsible for decisions regarding the avoidance of marine mammal interactions with survey gear through the application of best professional judgment) learns from the prior experience of all relevant NWFSC personnel (rather than from solely their own experience). The outcome should be increased transparency in decision-making processes where best professional judgment is appropriate and, to the extent possible, some degree of standardization across common situations, with an ultimate goal of reducing marine mammal interactions. It is the responsibility of the NWFSC to facilitate such exchange.

Handling Procedures and Data Collection

Improved standardization of handling procedures were discussed previously in “Mitigation.” In addition to the benefits implementing these protocols are believed to have on the animals through increased post-release survival, NWFSC believes adopting these protocols for data collection will also increase the information on which “serious injury” (SI) determinations (NMFS, 2012a, b) are based and improve scientific knowledge about marine mammals that interact with fisheries research gears and the factors that contribute to these interactions. NWFSC personnel will be provided standard guidance and training regarding handling of marine mammals, including how to identify different species, bring an individual aboard a vessel, assess the level of consciousness, remove fishing gear, return an individual to water and log activities pertaining to the interaction.

NWFSC will record interaction information on either existing data forms created by other NMFS programs or will develop their own standardized forms. To aid in SI determinations and comply with the current NMFS Serious Injury Guidelines (NMFS, 2012a, b), researchers will also answer a series of supplemental questions on the details of marine mammal interactions.

Finally, for any marine mammals that are killed during fisheries research activities, scientists will collect data and samples pursuant to Appendix D of the NWFSC DEA, “Protected Species Handling Procedures for NWFSC Fisheries Research Vessels.”

Reporting

As is normally the case, NWFSC will coordinate with the relevant stranding coordinators for any unusual marine mammal behavior and any stranding, beached live/dead, or floating marine mammals that are encountered during field research activities. The NWFSC will follow a phased approach with regard to the cessation of its activities and/or reporting of such events, as described in the proposed regulatory texts following this preamble. In addition, CSs or the cruise leader will provide reports to NWFSC leadership and to the Office of Protected Resources (OPR). As a result, when marine mammals interact with survey gear, whether killed or released alive, a report provided by the CS will fully describe any observations of the animals, the context (vessel and conditions), decisions made and rationale for decisions made in vessel and gear handling. The circumstances of these events are critical in enabling NWFSC and OPR to better evaluate the conditions under which takes are most likely occur. We believe in the long term this will allow the avoidance of these types of events in the future.

The NWFSC will submit annual summary reports to OPR including: (1) Annual line-kilometers surveyed during which the EK60, ME70, SX90 (or equivalent sources) were predominant (see “Estimated Take by Acoustic Harassment” for further discussion), specific to each region; (2) summary information regarding use of all hook and line, seine, and trawl gear, including number of sets, hook hours, tows, etc., specific to each research area and gear; (3) accounts of all incidents of marine mammal interactions, including circumstances of the event and descriptions of any mitigation procedures implemented or not implemented and why; (4) summary information related to any disturbance of pinnipeds, including event-specific

total counts of animals present, counts of reactions according to the three-point scale shown in Table 5, and distance of closest approach; and (5) a written evaluation of the effectiveness of NWFSC mitigation strategies in reducing the number of marine mammal interactions with survey gear, including best professional judgment and suggestions for changes to the mitigation strategies, if any. The period of reporting will be annually, beginning one year post-issuance of any LOA, and the report must be submitted not less than ninety days following the end of a given year. Submission of this information is in service of an adaptive management framework allowing NMFS to make appropriate modifications to mitigation and/or monitoring strategies, as necessary, during the five-year period of validity for these regulations.

NMFS has established a formal incidental take reporting system, the Protected Species Incidental Take (PSIT) database, requiring that incidental takes of protected species be reported within 48 hours of the occurrence. The PSIT generates automated messages to NMFS leadership and other relevant staff, alerting them to the event and to the fact that updated information describing the circumstances of the event has been inputted to the database. The PSIT and CS reports represent not only valuable real-time reporting and information dissemination tools but also serve as an archive of information that may be mined in the future to study why takes occur by species, gear, region, etc.

NWFSC will also collect and report all necessary data, to the extent practicable given the primacy of human safety and the well-being of captured or entangled marine mammals, to facilitate SI determinations for marine mammals that are released alive. NWFSC will require that the CS complete data forms and address supplemental questions, both of which have been developed to aid in SI determinations. NWFSC understands the critical need to provide as much relevant information as possible about marine mammal interactions to inform decisions regarding SI determinations. In addition, the NWFSC will perform all necessary reporting to ensure that any incidental M/SI is incorporated as appropriate into relevant SARs.

Adaptive Management

The regulations governing the take of marine mammals incidental to NWFSC fisheries research survey operations contain an adaptive management component. The inclusion of an adaptive management component will

be both valuable and necessary within the context of five-year regulations for activities that have been associated with marine mammal mortality.

The reporting requirements associated with this final rule are designed to provide OPR with monitoring data from the previous year to allow consideration of whether any changes are appropriate. OPR and the NWFSC will meet annually to discuss the monitoring reports and current science and whether mitigation or monitoring modifications are appropriate. The use of adaptive management allows OPR to consider new information from different sources to determine (with input from the NWFSC regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or deletions). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of reducing adverse effects to marine mammals and if the measures are practicable.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring reports, as required by MMPA authorizations; (2) results from general marine mammal and sound research; and (3) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOAs.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by these actions. Therefore, we have determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

There are multiple marine mammal species listed under the ESA with confirmed or possible occurrence in the proposed specified geographical region. The authorization of incidental take pursuant to the NWFSC's specified activity would not affect any designated critical habitat. OPR requested initiation of consultation with NMFS's West Coast Regional Office (WCRO) under section 7 of the ESA on the promulgation of five-year regulations and the subsequent issuance of LOAs to NWFSC under section 101(a)(5)(A) of the MMPA.

On November 10, 2016, the WCRO issued a biological opinion to OPR and to the NWFSC (concerning the conduct

of the specified activities) which concluded that the issuance of the authorizations is not likely to jeopardize the continued existence of any listed species and is not likely to adversely affect any listed marine mammal species. The opinion also concluded that the issuance of the authorizations would not affect any designated critical habitat.

National Environmental Policy Act (NEPA)

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), as implemented by the regulations published by the Council on Environmental Quality (40 CFR parts 1500–1508), NWFSC prepared a Programmatic EA to consider the direct, indirect and cumulative effects to the human environment resulting from the described research activities. OPR made NWFSC's EA available to the public for review and comment, in relation to its suitability for adoption by OPR in order to assess the impacts to the human environment of issuance of regulations and subsequent LOA to NWFSC. Also in compliance with NEPA and the CEQ regulations, as well as NOAA Administrative Order 216–6, OPR relies on NWFSC's EA, which also addresses OPR's action of issuing incidental take authorizations to NWFSC, and signed a Finding of No Significant Impact (FONSI) on March 27, 2018. NWFSC's EA and OPR's FONSI for this action may be found online at www.nmfs.noaa.gov/pr/permits/incidental/research.htm.

Classification

Pursuant to the procedures established to implement Executive Order 12866, the Office of Management and Budget has determined that this rule is not significant.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration at the proposed rule stage that this rule will not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis is not required and none has been prepared.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information (COI) subject

to the requirements of the Paperwork Reduction Act (PRA) unless that COI displays a currently valid OMB control number. This rule does not contain a COI requirement subject to the provisions of the PRA because the applicant is a Federal agency.

List of Subjects in 50 CFR Part 219

Exports, Fish, Imports, Indians, Labeling, Marine mammals, Penalties, Reporting and recordkeeping requirements, Seafood, Transportation.

Dated: July 24, 2018.

Samuel D. Rauch III,

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

For reasons set forth in the preamble, NMFS amends 50 CFR part 219 as follows:

PART 219—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 219 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

■ 2. Add subpart E to part 219 to read as follows:

Subpart E—Taking Marine Mammals Incidental to Northwest Fisheries Science Center Fisheries Research in the Pacific Ocean

Sec.

- 219.41 Specified activity and specified geographical region.
- 219.42 Effective dates.
- 219.43 Permissible methods of taking.
- 219.44 Prohibitions.
- 219.45 Mitigation requirements.
- 219.46 Requirements for monitoring and reporting.
- 219.47 Letters of Authorization.
- 219.48 Renewals and modifications of Letters of Authorization.
- 219.49 [Reserved]
- 219.50 [Reserved]

Subpart E—Taking Marine Mammals Incidental to Northwest Fisheries Science Center Fisheries Research in the Pacific Ocean

§ 219.41 Specified activity and specified geographical region.

(a) Regulations in this subpart apply only to the National Marine Fisheries Service's (NMFS) Northwest Fisheries Science Center (NWFSC) and those persons it authorizes or funds to conduct activities on its behalf for the taking of marine mammals that occurs in the area outlined in paragraph (b) of this section and that occurs incidental to research survey program operations.

(b) The taking of marine mammals by NWFSC may be authorized in a Letter

of Authorization (LOA) only if it occurs within the California Current Ecosystem, including Puget Sound and the Columbia River.

§ 219.42 Effective dates.

Regulations in this subpart are effective from August 27, 2018, through August 28, 2023.

§ 219.43 Permissible methods of taking.

(a) Under LOAs issued pursuant to § 216.106 of this chapter and § 219.47, the Holder of the LOA (hereinafter "NWFSC") may incidentally, but not intentionally, take marine mammals within the area described in § 219.41(b) by Level B harassment associated with use of active acoustic systems and physical or visual disturbance of hauled-out pinnipeds and by Level A harassment, serious injury, or mortality associated with use of hook and line gear, trawl gear, and seine gear, provided the activity is in compliance with all terms, conditions, and requirements of the regulations in this subpart and the applicable LOA.

§ 219.44 Prohibitions.

Notwithstanding takings contemplated in § 219.41 and authorized by a LOA issued under § 216.106 of this chapter and § 219.47, no person in connection with the activities described in § 219.41 may:

- (a) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or a LOA issued under § 216.106 of this chapter and § 219.47;
- (b) Take any marine mammal not specified in such LOA;
- (c) Take any marine mammal specified in such LOAs in any manner other than as specified;
- (d) Take a marine mammal specified in such LOA if NMFS determines such taking results in more than a negligible impact on the species or stocks of such marine mammal; or
- (e) Take a marine mammal specified in such LOA if NMFS determines such taking results in an unmitigable adverse impact on the availability of such species or stock of marine mammal for taking for subsistence uses.

§ 219.45 Mitigation requirements.

When conducting the activities identified in § 219.41(a), the mitigation measures contained in any LOA issued under § 216.106 of this chapter and § 219.47 must be implemented. These mitigation measures shall include but are not limited to:

- (a) General conditions:
 - (1) NWFSC shall take all necessary measures to coordinate and communicate in advance of each

specific survey with the National Oceanic and Atmospheric Administration's (NOAA) Office of Marine and Aviation Operations (OMAO) or other relevant parties on non-NOAA platforms to ensure that all mitigation measures and monitoring requirements described herein, as well as the specific manner of implementation and relevant event-contingent decision-making processes, are clearly understood and agreed upon;

(2) NWFSC shall coordinate and conduct briefings at the outset of each survey and as necessary between ship's crew (Commanding Officer/master or designee(s), as appropriate) and scientific party in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures;

(3) NWFSC shall coordinate as necessary on a daily basis during survey cruises with OMAO personnel or other relevant personnel on non-NOAA platforms to ensure that requirements, procedures, and decision-making processes are understood and properly implemented;

(4) When deploying any type of sampling gear at sea, NWFSC shall at all times monitor for any unusual circumstances that may arise at a sampling site and use best professional judgment to avoid any potential risks to marine mammals during use of all research equipment; and

(5) NWFSC shall implement handling and/or disentanglement protocols as specified in the guidance that shall be provided to NWFSC survey personnel.

(b) For all research surveys using trawl, hook and line, or seine gear in Puget Sound, the move-on rule mitigation protocol described in paragraph (c)(3) of this section shall be implemented upon observation of killer whales at any distance.

(c) Trawl survey protocols:

- (1) NWFSC shall conduct trawl operations as soon as is practicable upon arrival at the sampling station;
- (2) NWFSC shall initiate marine mammal watches (visual observation) a minimum of ten minutes prior to beginning of net deployment but shall also conduct monitoring during pre-set activities including trackline reconnaissance, CTD casts, and plankton or bongo net hauls. Marine mammal watches shall be conducted by scanning the surrounding waters with the naked eye and rangefinding binoculars (or monocular). During nighttime operations, visual observation shall be conducted using the naked eye and available vessel lighting;
- (3) NWFSC shall implement the move-on rule mitigation protocol, as

described in this paragraph. If one or more marine mammals are observed within 500 meters (m) of the planned location in the 10 minutes before setting the trawl gear, and are considered at risk of interacting with the vessel or research gear, or appear to be approaching the vessel and are considered at risk of interaction, NWFSC shall either remain onsite or move on to another sampling location. If remaining onsite, the set shall be delayed. If the animals depart or appear to no longer be at risk of interacting with the vessel or gear, a further 10 minute observation period shall be conducted. If no further observations are made or the animals still do not appear to be at risk of interaction, then the set may be made. If the vessel is moved to a different section of the sampling area, the move-on rule mitigation protocol would begin anew. If, after moving on, marine mammals remain at risk of interaction, the NWFSC shall move again or skip the station. Marine mammals that are sighted further than 500 m from the vessel shall be monitored to determine their position and movement in relation to the vessel to determine whether the move-on rule mitigation protocol should be implemented. NWFSC may use best professional judgment in making these decisions;

(4) NWFSC shall maintain visual monitoring effort during the entire period of time that trawl gear is in the water (*i.e.*, throughout gear deployment, fishing, and retrieval). If marine mammals are sighted before the gear is fully removed from the water, NWFSC shall take the most appropriate action to avoid marine mammal interaction. NWFSC may use best professional judgment in making this decision;

(5) If trawling operations have been suspended because of the presence of marine mammals, NWFSC may resume trawl operations when practicable only when the animals are believed to have departed the area. NWFSC may use best professional judgment in making this determination;

(6) When conducting surface trawls using the Nordic 264 net, dedicated crew with no other tasks shall conduct required marine mammal monitoring. Marine mammal monitoring shall be staffed in a stepwise process, with a minimum of two observers beginning pre-set monitoring and increasing to a minimum of four observers prior to and during gear deployment. During the tow, a minimum of three observers shall conduct required monitoring;

(7) NWFSC shall implement standard survey protocols to minimize potential for marine mammal interactions, including maximum tow durations at

target depth and maximum tow distance, and shall carefully empty the trawl as quickly as possible upon retrieval. Trawl nets must be cleaned prior to deployment;

(8) NWFSC must install and use a marine mammal excluder device at all times when the Nordic 264 trawl net is used;

(9) NWFSC must install and use acoustic deterrent devices whenever the Nordic 264 trawl net is used, with two pairs of the devices installed near the net opening. NWFSC must ensure that the devices are operating properly before deploying the net;

(10) For use of the Kodiak surface trawl in Puget Sound, trawl survey protocols described in this section apply only to cetaceans; and

(11) Trawl survey protocols described in this section do not apply to use of pair trawl gear in the Columbia River.

(d) Hook and line (including longline) survey protocols:

(1) NWFSC shall deploy hook and line gear as soon as is practicable upon arrival at the sampling station;

(2) NWFSC shall initiate marine mammal watches (visual observation) no less than 30 minutes prior to both deployment and retrieval of longline gear. Marine mammal watches shall be conducted by scanning the surrounding waters with the naked eye and range-finding binoculars (or monocular). During nighttime operations, visual observation shall be conducted using the naked eye and available vessel lighting;

(3) NWFSC shall implement the move-on rule mitigation protocol, as described in this paragraph. If one or more marine mammals are observed within 500 m of the planned location in the ten minutes before gear deployment, and are considered at risk of interacting with the vessel or research gear, or appear to be approaching the vessel and are considered at risk of interaction, NWFSC shall either remain onsite or move on to another sampling location. If remaining onsite, the set shall be delayed. If the animals depart or appear to no longer be at risk of interacting with the vessel or gear, a further 10 minute observation period shall be conducted. If no further observations are made or the animals still do not appear to be at risk of interaction, then the set may be made. If the vessel is moved to a different section of the sampling area, the move-on rule mitigation protocol would begin anew. If, after moving on, marine mammals remain at risk of interaction, the NWFSC shall move again or skip the station. Marine mammals that are sighted further than 500 m from the vessel shall be

monitored to determine their position and movement in relation to the vessel to determine whether the move-on rule mitigation protocol should be implemented. NWFSC may use best professional judgment in making these decisions;

(4) NWFSC shall maintain visual monitoring effort during the entire period of gear deployment and retrieval. If marine mammals are sighted before the gear is fully deployed or retrieved, NWFSC shall take the most appropriate action to avoid marine mammal interaction. NWFSC may use best professional judgment in making this decision;

(5) If deployment or retrieval operations have been suspended because of the presence of marine mammals, NWFSC may resume such operations when practicable only when the animals are believed to have departed the area. NWFSC may use best professional judgment in making this decision;

(6) NWFSC shall implement standard survey protocols, including maximum soak durations and a prohibition on chumming; and

(7) For hook and line surveys in Puget Sound, but not including longline surveys, hook and line survey protocols described in this section apply only to cetaceans.

(e) Seine survey protocols:

(1) NWFSC shall conduct seine operations as soon as is practicable upon arrival at the sampling station;

(2) NWFSC shall conduct marine mammal watches (visual observation) prior to beginning of net deployment. Marine mammal watches shall be conducted by scanning the surrounding waters with the naked eye and range-finding binoculars (or monocular);

(3) NWFSC shall implement the move-on rule mitigation protocol, as described in this paragraph for use of purse seine gear. If one or more small cetaceans (*i.e.*, dolphin or porpoise) or five or more pinnipeds are observed within 500 m of the planned location before setting the seine gear, and are considered at risk of interacting with the vessel or research gear, or appear to be approaching the vessel and are considered at risk of interaction, NWFSC shall either remain onsite or move on to another sampling location. If remaining onsite, the set shall be delayed. If the animals depart or appear to no longer be at risk of interacting with the vessel or gear, a further ten minute observation period shall be conducted. If no further observations are made or the animals still do not appear to be at risk of interaction, then the set may be made. If the vessel is moved to

a different area, the move-on rule mitigation protocol would begin anew. If, after moving on, marine mammals remain at risk of interaction, the NWFSC shall move again or skip the station. Marine mammals that are sighted further than 500 m from the vessel shall be monitored to determine their position and movement in relation to the vessel to determine whether the move-on rule mitigation protocol should be implemented. NWFSC may use best professional judgment in making these decisions;

(4) NWFSC shall maintain visual monitoring effort during the entire period of time that seine gear is in the water (*i.e.*, throughout gear deployment, fishing, and retrieval). If marine mammals are sighted before the gear is fully removed from the water, NWFSC shall take the most appropriate action to avoid marine mammal interaction. NWFSC may use best professional judgment in making this decision;

(5) If seine operations have been suspended because of the presence of marine mammals, NWFSC may resume seine operations when practicable only when the animals are believed to have departed the area. NWFSC may use best professional judgment in making this determination;

(6) If any cetaceans are observed in a purse seine net, NWFSC shall immediately open the net and free the animals; and

(7) NWFSC shall not make beach seine sets within 200 m of any hauled-out pinniped, and shall immediately remove the gear from the water upon observation of any marine mammal attempting to interact with the gear.

§ 219.46 Requirements for monitoring and reporting.

(a) NWFSC shall designate a compliance coordinator who shall be responsible for ensuring compliance with all requirements of any LOA issued pursuant to § 216.106 of this chapter and § 219.47 and for preparing for any subsequent request(s) for incidental take authorization.

(b) Visual monitoring program:

(1) Marine mammal visual monitoring shall occur prior to deployment of trawl, seine, and hook and line gear, respectively; throughout deployment of gear and active fishing of research gears (not including longline soak time); prior to retrieval of longline gear; and throughout retrieval of all research gear;

(2) Marine mammal watches shall be conducted by watch-standers (those navigating the vessel and/or other crew) at all times when the vessel is being operated; and

(3) NWFSC shall conduct census counts of established pinniped haulouts in the Columbia River and Puget Sound that are disturbed by NWFSC research activity, and shall record disturbance of hauled-out pinnipeds due to NWFSC research activity, paying particular attention to the distance at which different species of pinniped are disturbed. Disturbance shall be recorded according to a three-point scale of response severity.

(c) Training:

(1) NWFSC must conduct annual training for all chief scientists and other personnel who may be responsible for conducting dedicated marine mammal visual observations to explain mitigation measures and monitoring and reporting requirements, mitigation and monitoring protocols, marine mammal identification, completion of datasheets, and use of equipment. NWFSC may determine the agenda for these trainings;

(2) NWFSC shall also dedicate a portion of training to discussion of best professional judgment, including use in any incidents of marine mammal interaction and instructive examples where use of best professional judgment was determined to be successful or unsuccessful; and

(3) NWFSC shall coordinate with NMFS's Southwest Fisheries Science Center (SWFSC) regarding surveys conducted in the California Current Ecosystem, such that training and guidance related to handling procedures and data collection is consistent.

(d) Handling procedures and data collection:

(1) NWFSC must develop and implement standardized marine mammal handling, disentanglement, and data collection procedures. These standard procedures will be subject to approval by NMFS's Office of Protected Resources (OPR);

(2) When practicable, for any marine mammal interaction involving the release of a live animal, NWFSC shall collect necessary data to facilitate a serious injury determination;

(3) NWFSC shall provide its relevant personnel with standard guidance and training regarding handling of marine mammals, including how to identify different species, bring an individual aboard a vessel, assess the level of consciousness, remove fishing gear, return an individual to water, and log activities pertaining to the interaction; and

(4) NWFSC shall record such data on standardized forms, which will be subject to approval by OPR. NWFSC shall also answer a standard series of supplemental questions regarding the

details of any marine mammal interaction.

(e) Reporting:

(1) NWFSC shall report all incidents of marine mammal interaction to NMFS's Protected Species Incidental Take database within 48 hours of occurrence and shall provide supplemental information to OPR upon request. Information related to marine mammal interaction (animal captured or entangled in research gear) must include details of survey effort, full descriptions of any observations of the animals, the context (vessel and conditions), decisions made, and rationale for decisions made in vessel and gear handling;

(2) Annual reporting:

(i) NWFSC shall submit an annual summary report to OPR not later than 90 days following the end of a given year. NWFSC shall provide a final report within thirty days following resolution of comments on the draft report:

(ii) These reports shall contain, at minimum, the following:

(A) Annual line-kilometers surveyed during which the EK60, ME70, SX90 (or equivalent sources) were predominant and associated pro-rated estimates of actual take;

(B) Summary information regarding use of all hook and line, seine, and trawl gear, including number of sets, hook hours, tows, etc., specific to each gear;

(C) Accounts of all incidents of marine mammal interactions, including circumstances of the event and descriptions of any mitigation procedures implemented or not implemented and why;

(D) Summary information related to disturbance of hauled-out pinnipeds, including event-specific total counts of animals present, counts of reactions according to the three-point scale, and distance of closest approach;

(E) A written evaluation of the effectiveness of NWFSC mitigation strategies in reducing the number of marine mammal interactions with survey gear, including best professional judgment and suggestions for changes to the mitigation strategies, if any;

(F) Final outcome of serious injury determinations for all incidents of marine mammal interactions where the animal(s) were released alive; and

(G) A summary of all relevant training provided by NWFSC and any coordination with SWFSC or NMFS's West Coast Regional Office.

(f) Reporting of injured or dead marine mammals:

(1) In the unanticipated event that the activity defined in § 219.41(a) clearly causes the take of a marine mammal in a prohibited manner, NWFSC personnel

engaged in the research activity shall immediately cease such activity until such time as an appropriate decision regarding activity continuation can be made by the NWFSC Director (or designee). The incident must be reported immediately to OPR and the West Coast Regional Stranding Coordinator, NMFS. OPR will review the circumstances of the prohibited take and work with NWFSC to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. The immediate decision made by NWFSC regarding continuation of the specified activity is subject to OPR concurrence. The report must include the following information:

- (i) Time, date, and location (latitude/longitude) of the incident;
- (ii) Description of the incident;
- (iii) Environmental conditions (*e.g.*, wind speed and direction, Beaufort sea state, cloud cover, visibility);
- (iv) Description of all marine mammal observations in the 24 hours preceding the incident;
- (v) Species identification or description of the animal(s) involved;
- (vi) Status of all sound source use in the 24 hours preceding the incident;
- (vii) Water depth;
- (viii) Fate of the animal(s); and
- (ix) Photographs or video footage of the animal(s);

(2) In the event that NWFSC discovers an injured or dead marine mammal and determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.*, in less than a moderate state of decomposition), NWFSC shall immediately report the incident to OPR and the West Coast Regional Stranding Coordinator, NMFS. The report must include the information identified in paragraph (f)(1) of this section. Activities may continue while OPR reviews the circumstances of the incident. OPR will work with NWFSC to determine whether additional mitigation measures or modifications to the activities are appropriate;

(3) In the event that NWFSC discovers an injured or dead marine mammal and determines that the injury or death is not associated with or related to the activities defined in § 219.41(a) (*e.g.*, previously wounded animal, carcass with moderate to advanced decomposition, scavenger damage), NWFSC shall report the incident to OPR and the West Coast Regional Stranding Coordinator, NMFS, within 24 hours of the discovery. NWFSC shall provide photographs or video footage or other

documentation of the stranded animal sighting to OPR.

§ 219.47 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to these regulations, NWFSC must apply for and obtain a Letter of Authorization (LOA).

(b) An LOA, unless suspended or revoked, may be effective for a period of time not to exceed the expiration date of these regulations.

(c) If an LOA expires prior to the expiration date of these regulations, NWFSC may apply for and obtain a renewal of the LOA.

(d) In the event of projected changes to the activity or to mitigation and monitoring measures required by an LOA, NWFSC must apply for and obtain a modification of the LOA as described in § 219.48 of this chapter.

(e) The LOA shall set forth:

(1) Permissible methods of incidental taking;

(2) Means of effecting the least practicable adverse impact (*i.e.*, mitigation) on the species, its habitat, and on the availability of the species for subsistence uses; and

(3) Requirements for monitoring and reporting.

(f) Issuance of the LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations.

(g) Notice of issuance or denial of an LOA shall be published in the **Federal Register** within thirty days of a determination.

§ 219.48 Renewals and modifications of Letters of Authorization.

(a) An LOA issued under § 216.106 of this chapter and § 219.47 for the activity identified in § 219.41(a) shall be renewed or modified upon request by the applicant, provided that:

(1) The proposed specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for these regulations (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section), and

(2) OPR determines that the mitigation, monitoring, and reporting measures required by the previous LOA under these regulations were implemented.

(b) For an LOA modification or renewal requests by the applicant that include changes to the activity or the mitigation, monitoring, or reporting

measures (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section) that do not change the findings made for the regulations or result in no more than a minor change in the total estimated number of takes (or distribution by species or years), OPR may publish a notice of proposed LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under § 216.106 of this chapter and § 219.47 for the activity identified in § 219.41(a) may be modified by OPR under the following circumstances:

(1) Adaptive Management—OPR may modify (including augment) the existing mitigation, monitoring, or reporting measures (after consulting with NWFSC regarding the practicability of the modifications) if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring set forth in the preamble for these regulations;

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA:

(A) Results from NWFSC's monitoring from the previous year(s);

(B) Results from other marine mammal and/or sound research or studies; and

(C) Any information that reveals marine mammals may have been taken in a manner, extent or number not authorized by these regulations or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, OPR will publish a notice of proposed LOA in the **Federal Register** and solicit public comment.

(2) Emergencies—If OPR determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in LOAs issued pursuant to § 216.106 of this chapter and § 219.47, an LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within thirty days of the action.

§ 219.49 [Reserved]

§ 219.50 [Reserved]

[FR Doc. 2018–16115 Filed 7–26–18; 8:45 am]

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H.R. 1496/P.L. 115-207

To designate the facility of the United States Postal Service located at 3585 South Vermont Avenue in Los Angeles, California, as the "Marvin Gaye Post Office". (July 24, 2018; 132 Stat. 1536)

H.R. 2673/P.L. 115-208

To designate the facility of the United States Postal Service

located at 514 Broadway Street in Pekin, Illinois, as the "Lance Corporal Jordan S. Bastean Post Office". (July 24, 2018; 132 Stat. 1537)

H.R. 3183/P.L. 115-209

To designate the facility of the United States Postal Service located at 13683 James Madison Highway in Palmyra, Virginia, as the "U.S. Navy Seaman Dakota Kyle Rigsby Post Office". (July 24, 2018; 132 Stat. 1538)

H.R. 4301/P.L. 115-210

To designate the facility of the United States Postal Service located at 201 Tom Hall Street in Fort Mill, South Carolina, as the "J. Elliott Williams Post Office Building". (July 24, 2018; 132 Stat. 1539)

H.R. 4406/P.L. 115-211

To designate the facility of the United States Postal Service located at 99 Macombs Place in New York, New York, as the "Tuskegee Airmen Post Office Building". (July 24, 2018; 132 Stat. 1540)

H.R. 4463/P.L. 115-212

To designate the facility of the United States Postal Service located at 6 Doyers Street in New York, New York, as the "Mabel Lee Memorial Post Office". (July 24, 2018; 132 Stat. 1541)

H.R. 4574/P.L. 115-213

To designate the facility of the United States Postal Service located at 108 West Schick Road in Bloomingdale, Illinois, as the "Bloomingdale Veterans Memorial Post Office Building". (July 24, 2018; 132 Stat. 1542)

H.R. 4646/P.L. 115-214

To designate the facility of the United States Postal Service located at 1900 Corporate Drive in Birmingham, Alabama, as the "Lance Corporal Thomas E. Rivers, Jr. Post Office Building". (July 24, 2018; 132 Stat. 1543)

H.R. 4685/P.L. 115-215

To designate the facility of the United States Postal Service located at 515 Hope Street in Bristol, Rhode Island, as the "First Sergeant P. Andrew McKenna Jr. Post Office". (July 24, 2018; 132 Stat. 1544)

H.R. 4722/P.L. 115-216

To designate the facility of the United States Postal Service located at 111 Market Street in Saugerties, New York, as the "Maurice D. Hinchey Post Office Building". (July 24, 2018; 132 Stat. 1545)

H.R. 4840/P.L. 115-217

To designate the facility of the United States Postal Service

located at 567 East Franklin Street in Oviedo, Florida, as the "Sergeant First Class Alwyn Crendall Cashe Post Office Building". (July 24, 2018; 132 Stat. 1546)

H.R. 5956/P.L. 115-218

Northern Mariana Islands U.S. Workforce Act of 2018 (July 24, 2018; 132 Stat. 1547)

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